Wisconsin Chapter HFS 157 - Radiation Protection Regulatory Guide July, 2003

Guidance for Licenses of Broad Scope

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EXECUTIVE SUMMARY

Wisconsin Regulatory Guides (WISREGS) are issued to describe and make available to the applicant or licensee, acceptable methods of implementing specific parts of Wisconsin Administrative Code, Chapter HFS 157 'Radiation Protection,' to delineate techniques used by Department of Health and Family Services (DHFS) staff in evaluating past specific problems or postulated accidents, and to provide guidance to applicantsor licensees. WISREGS are not substitutes for Chapter HFS 157 'Radiation Protection', therefore compliance with them is not required. Methods and solutions different from those set forth in this guide will be acceptable if they provide a basis for the Department of Health and Family Services (DHFS), Radiation Protection Section to determine if a radiation protection program meets the current rule and protects public health and safety.

Comments and suggestions for improvements in this WISREG are encouraged. This WISREG will be revised, as appropriate, to accommodate comments and to reflect new information or experience. Comments should be sent to **Department of Health and Family Services, Radiation Protection Section, P.O. Box 2659, Madison, WI 53701-2659.**

To request copies of this guide (which may be reproduced) call DHFS, Radiation Protection Section at (608) 267-4797 or for electronic copy go to our web site at: http://dhfs.wisconsin.gov/dph_beh/RadioactiveMat/IndexRM.htm.

This WISREG "Guidance for Licenses of Broad Scope" has been developed to streamline the application process for a Broad Scope License. A copy of the application DPH form 45015 "Application for Radioactive Material License for Broad Scope" is located in **Appendix A** of this guide.

Appendix C **through** V provides examples, models and additional information that can be used when completing the application.

It typically takes 60-90 days for a license to be processed and issued if the application is complete. When submitting the application be sure to include the appropriate application fee listed in *HFS 157.10* for a Broad Scope license.

In summary, the applicant will need to do the following to submit an application for a Broad Scope license:

- Use this regulatory guide to prepare the application DPH form 45015 "Application for Radioactive Material License for Broad Scope" (Appendix A).
- Complete the application DPH form 45015 "Application for Radioactive Material License for Broad Scope" (Appendix A). See 'Contents of Application' of the guide for additional information.
- Include any additional attachments.
 - All supplemental pages should be on 8 ½" x 11" paper.
 - Please identify all attachments with the applicant's name and license number (if a renewal).
- Avoid submitting proprietary information unless it is absolutely necessary.
- Submit an original signed application along with attachments (if any) and if possible a copy on a diskette or CD (Microsoft Word is preferred).
- Submit the application fee.
- Retain one copy of the licensee application and attachments (if any) for your future reference. You
 will need this information because the license will require that radioactive material be possessed and
 used in accordance with statements, representation, and procedures provided in the application and
 supporting documentation.

If you have any questions about the application process please contact DHFS, Radiation Protection Section at (608) 267-4797.

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ABBREVIATIONS

ALI annual limit on intake

ALARA as low as is reasonably achievable ANSI American National Standards Institute

Bq Becquerel

CFR Code of Federal Regulations

cpm counts per minute

Ci Curie

DFP Decommissioning Funding Plan

DHFS Department of Health and Family Services (State of Wisconsin)

DIS decay-in-storage

DOE United States Department of Energy

DOT United States Department of Transportation

DPH Division of Public Health dpm disintegrations per minute

EPA United States Environmental Protection Agency

GBq Gigabecquerel G-M Geiger-Mueller

GPO Government Printing Office

IAEA International Atomic Energy Agency

IN Information Notice kBq Kilobecquerel

LLW Low Level Radioactive Waste

 $\begin{array}{ll} MBq & Megabequerel \\ \mu Ci & Microcurie \\ mCi & Millicuries \\ mR & Milliroentgen \\ mrem & Millirem \\ mSv & Millisievert \end{array}$

NMSS NRC Office of Nuclear Material Safety and Safeguards

NRC United States Nuclear Regulatory Commission

NVLAP National Voluntary Laboratory Accreditation Program

R Roentgen

RG Regulatory Guide

RSC Radiation Safety Committee RSO Radiation Safety Officer

SI International System of Units (abbreviated SI from the French Le Systeme Internationale

d'Unites)

SSD Sealed Source and Device

Sv Sievert

TEDE Total Effective Dose Equivalent

PURPOSE OF GUIDE

This document provides guidance to an applicant in preparing a broad scope license application and describes the criteria used by DHFS staff when evaluating the application. An applicant for a limited scope license generally must submit to the DHFS, for review and approval, the specific training and experience of each proposed user and the facilities and equipment available to support each proposed use; an applicant for a broad scope license normally must submit to the DHFS, for review and approval, a description of the internal review process and criteria that will be used to approve users and uses. As opposed to limited scope licenses, which typically identify specific isotopes that may be possessed, the broad scope license generally authorizes the possession and use of a wide range of radioactive materials.

Because DHFS grants significant decision making authority to broad scope licensees through the license, a broad scope license is not normally issued to a new licensee. An applicant for a broad scope license typically has several years of experience operating under a limited scope license and a good regulatory performance history. This document is intended to provide the additional guidance required by the experienced limited scope licensee to prepare an application for a broad scope license. Guidance related to specific program areas, which may not apply to all broad scope licensees, is not included in this document but can be found in other volumes of WISREGS-1556, often referred to in this document as "the base WISREGs" or "the base documents," or in guidance documents that have not yet undergone the consolidation process.

Applicants are expected to have first established limited scope licensed programs in accordance with the guidance described in the appropriate base WISREG(s) and then use this document to complete the application for broad scope license. For example, applicants for a broad scope license who use radioactive material for research and development should review WISREG-1556, Volume 7, "Guidance For Academic, Research and Development, and Other Licenses of Limited Scope," for guidance. Similarly, applicants for broad scope license who use radioactive material for medical purposes should review WISREG-1556, Volume 9, "Guidance For Medical Use of Radioactive Material."

HFS 157.13(3)(a), "Special Requirements for Specific Licenses of Broad Scope", provides for three distinct categories of broad scope license, i.e., Type A, Type B, and Type C, which are defined in *HFS 157.13(3)(b)*.

Type A licenses of broad scope are typically the largest licensed programs and encompass a broad range of uses. Type A broad scope licensees use a Radiation Safety Committee (RSC), Radiation Safety Officer (RSO), and criteria developed and submitted by the licensee and approved by DHFS during the licensing process, to review and approve all uses and users under the license. The requirements for issuance of a Type A broad scope license are described in *HFS 157.13(3)*. An applicant for a Type A broad scope license must establish administrative controls and provisions relating to organization and management, procedures, recordkeeping, material control, and accounting and management review that are necessary to assure safe operations, including:

- Establishment of a RSC
- Appointment of a qualified RSO
- Establishment of appropriate administrative procedures to assure:
 - -control of procurement and use of radioactive material;
 - -completion of safety evaluations of proposed uses that take into consideration adequacy of facilities and equipment, training and experience of the user, and operating and handling procedures; and
 - -review, approval, and recording by the RSC of safety evaluations of proposed uses.

Type B broad scope licensed programs are normally smaller and less diverse than Type A broad scope programs. Type B broad scope licensees use an RSO and criteria developed and submitted by the licensee and approved by DHFS during the licensing process, to review and approve all uses and users under the license. Because the RSO reviews and approves all uses and users under the license, and not a full RSC as established for Type A broad scope programs, the types and quantities of radioactive material authorized by the Type B broad scope license are limited to those described in *HFS 157.13(3)(b)* and **Chapter HFS 157 'Radiation Protection', Appendix C.** While the quantities of individual radionuclides described in **Chapter HFS 157 'Radiation Protection', Appendix C** may be large, total license possession limits are further restricted by the Unity Rule (see **Item 9,** "Unsealed and/or Sealed Radioactive Material", for additional information on license possession limits and the Unity Rule). Generally, the scope of authorization for Type B licenses is limited to the experience and knowledge of the RSO. The requirements for issuance of a Type B broad scope license are described in **HFS 157.13 (3)(d)**.

An applicant for a Type B broad scope license must also establish administrative controls and provisions relating to organization and management, procedures, recordkeeping, material control, and accounting and management review that are necessary to assure safe operations, including:

- Appointment of a qualified RSO
- Establishment of appropriate administrative procedures to assure:
 - -control of procurement and use of radioactive material;
 - -completion of safety evaluations of proposed uses that take into consideration adequacy of facilities and equipment, training and experience of the user, and operating and handling procedures; and
 - -review, approval, and recording by the RSO of safety evaluations of proposed uses.

Type C broad scope licensed programs are typically issued to institutions that do not require significant quantities of radioactive material but need the flexibility to possess a variety of different radioactive materials. Users of licensed material under these programs are approved by the licensee based on training and experience criteria described in *HFS 157.13(3)(e)*. The types and quantities of radioactive material authorized by the Type C broad scope license are limited to those described in *HFS 157.13(3)(b)* and **Chapter HFS 157 'Radiation Protection' Appendix C**, again, considering the Unity Rule. The requirements for issuance of a Type C broad scope license are described in *HFS 157.13(3)(e)*. While *HFS 157.13(3)(e)* does not require Type C broad scope licensees to appoint an RSO, the licensee must establish administrative controls and provisions relating to procurement of radioactive material, procedures, recordkeeping, material control and accounting, and management review to assure safe operations. This should include the appointment of someone responsible for the day-to-day operation of the Radiation Safety Program, such as an RSO.

Except for activities specifically excluded from broad scope licenses by *HFS 157.13(3)(f)*, a Type A broad scope license can include any licensed material the applicant needs and for which it qualifies. An application for a Type A broad scope license can include uses of source material and special nuclear material under the same program (e.g., laboratory-scale research and development or the use of uranium as shielding) as the radioactive material to be possessed under the provisions of *HFS 157.13(1)* and **Chapter HFS 157 'Radiation Protection' Appendix P**. However, applicants should submit separate applications for the use of source and special nuclear materials for purposes not directly related to the use

of radioactive material under the Type A broad scope license (e.g., use of source material in subcritical assemblies and special nuclear material in cardiac pacemakers).

Types B and C broad scope licenses are restricted in their possession of radioactive material by *HFS* 157.13(3)(b) and Chapter HFS 157 'Radiation Protection' Appendix C. Type B and Type C licensees who require materials not specified in Chapter HFS 157 'Radiation Protection' Appendix C will need to: (1) develop Type A broad scope programs, which would require a license amendment; or (2) carry these additional materials under a separate specific license of limited scope. The latter option would require that the licensee review the base WISREG related to the specific use of this material and submit the information required by the license reviewer as described in that document. For example, applicants who require materials not specified in Chapter HFS 157 'Radiation Protection' Appendix C for purposes of research and development should review WISREG-1556, Volume 7, "Guidance For Academic, Research and Development, and Other Licenses of Limited Scope" and submit the information described therein. Licensees are reminded that changes to the specific license of limited scope require amendment of the license.

Type B licensees who require quantities of material specified in **Chapter HFS 157 'Radiation Protection' Appendix C**, but in excess of that prescribed by *HFS 157.13(3)(b)*, will need to: (1) develop a Type A broad scope program; or (2) carry these additional materials under a separate specific license of limited scope, as described in the previous paragraph. Type C licensees who require quantities of material specified in **Chapter HFS 157 'Radiation Protection' Appendix C**, but in excess of that prescribed by *HFS 157.13(3)(b)*, will need to: (1) develop, as appropriate, a Type A or Type B broad scope program; or (2) carry these additional materials under a specific license of limited scope. Once again, changes to the specific license of limited scope require amendment of the license.

In practice, *HFS 157.13(3)* reduces the administrative burden for both licensees and DHFS without reducing the safety standards or lessening the licensing requirements for training, experience, facilities, and equipment. Both DHFS and the licensee benefit from the reduction in license amendments that might otherwise be needed to change authorized radionuclides, quantities, or names of individuals who may use, or supervise the use of, radioactive material.

HFS 157.13(3) does not specifically permit a broad scope licensee to make other types of changes to the radiation program as described in the application. However, DHFS has permitted broad scope licensees, on a case by case basis, to build in limited program flexibility during the licensing process. DHFS will continue to allow licensees to build in this type of program flexibility.

Through license condition, DHFS will provide even greater flexibility to Type A broad scope licensees who have developed an adequate radiation safety program oversight structure. Type A broad scope licensees and applicants for Type A broad scope license who specify the duties and responsibilities of management, the RSC, and the RSO, including: (1) review and approval of program and procedural changes by the RSC; (2) implementation of program and procedural changes; (3) audit of licensed operations to determine compliance; and (4) taking appropriate actions when noncompliance is identified, including analysis of the cause, corrective actions, and actions to prevent recurrence, will be authorized, through use of the license condition listed below, to make some program changes and to revise some procedures previously approved by DHFS without amendment of the license as long as the program change or revised procedure:

- Is reviewed and approved by the RSC prior to implementation;
- Satisfies regulatory requirements;
- Does not change existing license conditions; and
- Does not decrease the effectiveness of the Radiation Safety Program.

For Type A broad scope applicants or licensees requesting this additional flexibility, a clear description of the process for procedure and program review and approval must be provided. Applicants must describe how specific changes will be documented. At a minimum, documentation shall state the reason for the change and summarize the radiation safety matters that were considered prior to the approval of each change.

Type A Broad Scope License Condition Used to Grant Additional Flexibility:

Notwithstanding the requirements of License Condition Number (insert number of license
condition that incorporates the licensee's application and letters into the document), the licensee is
authorized to make program changes and changes to procedures specifically identified in the
(application dated or letter dated), which were previously approved by the Commission and
incorporated into the license, without prior DHFS approval, as long as:

- -The proposed revision is documented, reviewed, and approved by the licensee's Radiation Safety Committee in accordance with established procedures prior to implementation;
- -The revised program is in accordance with **Chapter HFS 157 'Radiation Protection'**, will not change license conditions, and will not decrease the effectiveness of the Radiation Safety Program;
- -The licensees staff is trained in the revised procedures prior to implementation; and
- -The licensees audit program evaluates the effectiveness of the change and its implementation.

The guidance that follows in this volume specifies that Type A broad scope licensees who have developed an adequate radiation safety program oversight structure may be granted the flexibility to make program changes and revise procedures in the areas of:

- Training for Individuals Working in or Frequenting Restricted Areas (Item 8)
- Audit Program (**Item 12.1**)
- Radiation Monitoring Instruments (**Item 12.2**)
- Material Receipt and Accountability (Item 12.3)
- Safe Use of Radionuclides and Emergency Procedures (Item 12.6)
- Surveys (**Item 12.8**)

This WISREG identifies the information needed to complete DPH Form 45015 "Application for Radioactive Material License for Broad Scope" (Appendix A), for the use of radioactive material for licenses of broad scope.

The format within this WISREG for each item of technical information is as follows:

- Rule -- references the requirements of Chapter HFS 157 'Radiation Protection' applicable to the item
- Criteria -- outlines the criteria used to judge the adequacy of the applicant's response
- **Discussion** -- provides additional information on the topic sufficient to meet the needs of most readers
- **Response from Applicant** -- provides suggested response(s), offers the option of an alternative reply, or indicates that no response is needed on that topic during the licensing process.

As indicated on the application, the answers to some items are to be provided on separate sheets of paper and submitted with the completed DPH Form 45015 "Application for Radioactive Material License for Broad Scope" (Appendix A).

The information submitted in the application must be sufficient to demonstrate that proposed equipment, facilities, personnel, and procedures are adequate to protect the health and safety of the citizens of Wisconsin according to DHFS's guidelines. Submission of incomplete or inadequate information will result in delays in the approval process for the license. Additional information will be requested when necessary to ensure that an adequate radiation safety program has been established. Such requests for additional information will be requested when necessary. Such requests for additional information will delay completion of the application's review and may be avoided by a thorough study of the rule(s) and these instructions prior to submitting the application.

WHO REGULATES FACILITIES IN WISCONSIN?

In the special situation of work at federally controlled sites in Wisconsin, it is necessary to know the jurisdictional status of the land to determine whether Nuclear Regulatory Commission (NRC) or DHFS has regulatory authority. The NRC has regulatory authority over land determined to be under "exclusive federal jurisdiction," while DHFS has jurisdiction over non-exclusive federal jurisdiction land (see **Table 1**). Applicants and licensees are responsible for finding out, in advance, the jurisdictional status of the specific areas where they plan to conduct licensed operations. DHFS recommends that applicants and licensees ask their local contacts for the federal agency controlling the site (e.g., contract officer, base environmental health officer, district office staff) to help determine the jurisdictional status of the land and to provide the information in writing, so that licensees can comply with NRC or DHFS regulatory requirements, as appropriate. The following table lists examples of regulation authority.

Table 1: Who Regulates the Activity?

| Applicant and Proposed Location of Work | Regulatory Agency |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|
| Federal agency regardless of location (except that Department of Energy [DOE] and, under most circumstances, its prime contractors are exempt from licensing [10 CFR 30.12]) | NRC |
| Non-federal entity in non-Agreement State (see map on next page), U.S. territory, or possession | NRC |
| Non-federal entity in WI at non-federally controlled site | DHFS |
| Non-federal entity in WI at federally-controlled site <i>not</i> subject to exclusive Federal jurisdiction | DHFS |
| Non-federal entity in WI at federally-controlled site subject to exclusive federal jurisdiction | NRC |

Locations of NRC Offices and Agreement States

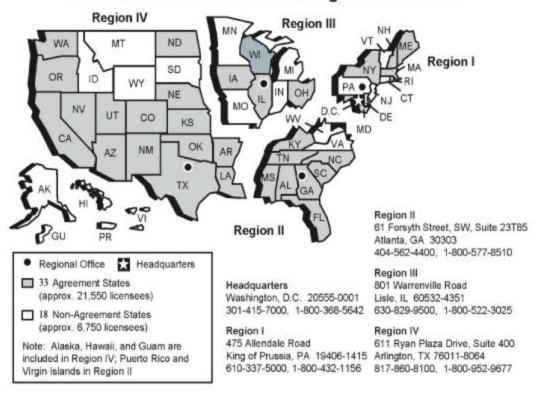


Figure 1: U.S. Map. Location of NRC Offices and Agreement States.

Reference: A current list of Agreement States (States that have entered into agreements with the NRC that give them the authority to license and inspect radioactive material used or possessed within their borders), (including names, addresses, and telephone numbers of responsible officials) may be obtained upon request from NRC's Regional Offices. NRC Office of State and Tribal Programs (STP) also provides the current list of Agreement States which can be found at http://www.hsrd.ornl.gov/nrc/home.html.

MANAGEMENT RESPONSIBILITY

DHFS recognizes that effective radiation safety program management is vital to achieving safe and compliant operations. DHFS also believes that consistent compliance with **Chapter HFS 157 'Radiation Protection'** provides reasonable assurance that licensed activities will be conducted safely. DHFS has found that effective management is key to a well-run radiation safety program. Management refers to a senior-level manager who has responsibility for overseeing licensed activities.

To ensure adequate management involvement, a management representative must sign the submitted application acknowledging management's commitments and responsibility for all the following:

- Radiation safety, security and control of radioactive materials, and compliance with Chapter HFS 157 'Radiation Protection';
- Completeness and accuracy of the radiation safety records and all information provided to DHFS;
- Knowledge about the contents of the license and application;
- Committing adequate resources (including space, equipment, personnel, time and if needed, contractors) to the radiation protection program to ensure that public and worker safety is protected from radiation hazards and compliance with the rule is maintained;
- Selecting and assigning a qualified individual to serve as the Radiation Safety Officer (RSO) for their licensed activities.

APPLICABLE RULE

It is the applicant's or licensee's responsibility to obtain, read and follow **Chapter HFS 157 'Radiation Protection'**.

The following subchapters of **Chapter HFS 157 'Radiation Protection'** contain requirements applicable to the use of licensed material by broad scope licensees:

| • | Subchapter I | "General" |
|---|-----------------|------------------------------------------------|
| • | Subchapter II | "Licensing of Radioactive Material" |
| • | Subchapter III | "Standards for Protection from Radiation" |
| • | Subchapter X | "Notices, Instructions and Reports to Workers" |
| • | Subchapter XI | "Inspection by DHFS" |
| • | Subchapter XII | "Enforcement" |
| • | Subchapter XIII | "Transportation " |

The following subchapters of **Chapter HFS 157 'Radiation Protection'** contain requirements which, depending on the type or types of activities authorized by the license, may be applicable to the use of licensed material by broad scope licensees:

| Subchapter IV | Radiation Safety Requirements for Industrial Radiographic Operations" |
|-----------------------------------|-----------------------------------------------------------------------------------------------|
| • Subchapter V | "Radiation Safety Requirements for Wireline Service Operations and Subsurface Tracer Studies" |
| Subchapter VI | "Medical Use of Radioactive Material" |
| • Subchapter VII | "Radiation Safety Requirements for Irradiators" |

To request copies of the above documents, call Department of Health and Family Services (DHFS), Radiation Protection Section at (608) 267-4797 or for electronic copy go to our web site at: http://dhfs.wisconsin.gov/dph_beh/RadioactiveMat/IndexRM.htm.

HOW TO FILE

PAPER APPLICATION

Applicants for a materials license should do the following:

- Be sure to use the current guidance from DHFS in preparing an application.
- Complete DPH form 45015 "Application for Radioactive Material License for Broad Scope" (Appendix A).
- For each separate sheet, other than submitted with the application, identify and key it to the item number on the application, or the topic to which it refers.
- Submit all documents on 8 ½ x 11 inch paper.
- Avoid submitting proprietary information unless it is absolutely necessary.
- Submit an original, signed application.
- Retain one copy of the license application for your future reference.

Deviations from the suggested wording of responses as shown in this WISREG or submission of alternative procedures will require a more detailed review.

Personal employee information, i.e., home address, home telephone number, Social Security Number, date of birth, and radiation dose information, should not be submitted unless specifically requested by DHFS.

WHERE TO FILE

Applicants wishing to possess or use radioactive material in Wisconsin are subject to the requirements of **Chapter HFS 157 'Radiation Protection'** and must file a license application with:

Department of Health and Family Services
Radiation Protection Section
P.O. Box 2659
Madison, WI 53701- 2659

LICENSE FEES

The appropriate fee must accompany each application or license amendment request. Refer to *HFS* 157.10 to determine the amount of the fee. DHFS will not issue the new license prior to fee receipt. Once the application review has begun, no fees will be refunded. Application fees will be charged regardless of DHFS's disposition of an application or the withdrawal of an application.

Licensees are also subject to annual fees; refer to HFS 157.10.

Direct all questions about DHFS's fees or completion of **Item 15** of DPH form 45015"Application for Radioactive Material License for Broad Scope" (**Appendix A**) to DHFS, Radiation Protection Section at (608) 267-4797.

CONTENTS OF AN APPLICATION

Item 1: License Action Type

| On the application check the appropriate box and list the license number for renewal and amendments. | | |
|------------------------------------------------------------------------------------------------------|----------------------------|--|
| Response from Applicant: | | |
| • | | |
| | | |
| Item 1 Type Of Ap | oplication (Check one box) | |

Item 2: Applicant's Name and Mailing Address

List the legal name of the applicant's corporation or other legal entity with direct control over use of the radioactive material; a division or department within a legal entity may not be a licensee. An individual may be designated as the applicant only if the individual is acting in a private capacity and the use of the radioactive material is not connected with employment in a corporation or other legal entity. Provide the mailing address where correspondence should be sent.

Response from Applicant:

| Item 2 Name And Mailing Address Of Applicant: |
|---------------------------------------------------|
| Applicant's Telephone Number (Include Area Code): |

Note: DHFS must be notified in the event of change of ownership or control and bankruptcy proceedings; see below for more details.

Timely Notification of Change of Ownership or Control:

Rule: HFS 157.13

Criteria: Licensees must provide full information and obtain DHFS's written consent prior to transferring

ownership or control of the license, or, as some licensees call it, "transferring the license."

Discussion: Changes in ownership may be the results of mergers, buyouts, or majority stock transfers.

Although it is not DHFS's intent to interfere with the business decisions of licensees, it is necessary for

licensees to obtain prior DHFS written consent. This is to ensure the following:

Radioactive materials are possessed, used, or controlled only by persons who have valid DHFS

licenses:

Materials are properly handled and secured;

Persons using these materials are competent and committed to implementing appropriate

radiological controls;

A clear chain of custody is established to identify who is responsible for final disposition of

records and radioactive materials;

The transferee has the financial resources to decommission the license, if necessary; and

Public health and safety are not compromised by the use of such materials.

Appendix H identifies the information to be provided about changes of ownership or control.

Notification of Bankruptcy Proceedings

Rule: *HFS 157.13(10)*

Criteria: Within 10 days following filing of voluntary or involuntary petition for bankruptcy for or

against a licensee, the licensee must notify DHFS in writing, identifying the bankruptcy court in which

the petition was filed and the date of filing.

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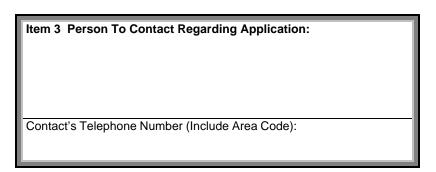
Item 3: Person to Contact Regarding Application

Identify the individual who can answer questions about the application and include his or her telephone number. This is typically the proposed radiation safety officer, unless the applicant has named a different person as the contact. DHFS will contact this individual if there are questions about the application.

Notify DHFS if the contact person or his or her telephone number changes so that DHFS can contact the applicant or licensee in the future with questions, concerns, or information. This notice is for "information only" and does not require a license amendment or a fee.

Applicants should note that deviations from the suggested responses and submission of alternative procedures may require custom review.

Response from Applicant:



Item 4: Address(es) Where Licensed Material Will Be Used or Possessed

Specify each proposed location of use by the street address, city, and state or other descriptive address (e.g., on Highway 10, 5 miles east of the intersection of Highway 10 and State Route 234, Anytown). The descriptive address should be sufficient to allow a DHFS inspector to find the facility location. **A Post**Office box address is not acceptable. If radioactive material is to be used at more than one location, give

the specific address of each location. Applicants for a broad scope license need not identify each facility at a particular address where radioactive material will be used. For example, applicants can specify that radioactive material will be used on the Main Campus of ABC University located in Anytown, WI.

Applicants should identify the location of all facilities designed or established for special uses, e.g., panoramic irradiators, interim or long-term waste storage facilities, high activity laboratories, iodination facilities, alpha laboratories, incinerators, and animal facilities (see **Item 11 'Facilities and Equipment'** for further guidance).

If radioactive material (e.g., portable gauging devices) will be used at temporary job sites, specify "temporary job sites anywhere in Wisconsin where DHFS maintains jurisdiction" and describe the scope of these activities.

If radioactive material is to be used in field studies, the activities must be specifically identified and authorized on the license. **Appendix I** contains information required of applicants prior to granting authorization for field use of licensed material.

A DHFS-approved license amendment identifying a new location of use, which is not encompassed by a location described on the existing license, is required before receiving, using and storing licensed material at that location.

Being granted a DHFS license does not relieve a licensee from complying with other applicable Federal, State, or local regulations (e.g., local zoning requirements for storage locations).

Response from Applicant:

| Item 4 Address(es) Where Radioactive Material Will Be Used Or Possessed (Do not use Post Office Box): | |
|----------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------|
| Address | Telephone Number (Include Area Code) |
| Address | Telephone Number (Include Area Code) |
| Address | Telephone Number (Include Area Code) |
| Is radioactive material used at locations for field studies, other off-site locations or special use facilities? Yes No | |
| If yes, please attach an additional sheet(s) with the locations address(es) a | and a list of activities to be conducted at each location. |

Note: As discussed later in Item 10 'Financial Assurance and Record keeping for Decommissioning,' licensees need to maintain permanent records on where licensed material was used or stored while the license was in force. This is important for making future determinations about the release of these locations for unrestricted use (e.g., before the license is terminated). Acceptable records are sketches, written descriptions of the specific locations, or room numbers where licensed material is used or stored and any records of spills or other unusual occurrences involving the spread of contamination in or around the licensee's facilities.

INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM

Item 5: Executive Management

Rule: HFS 157.21; HFS 157.13(3)(c); HFS 157.13(3)(d); HFS 157.13(3)(e).

Criteria: The applicant must have administrative controls and provisions relating to organization and management and management review necessary to assure safe operations.

Discussion: Executive management is the individual at the senior management level who is responsible for oversight of the radiation safety program and has the ultimate responsibility for the license and the activities associated with the license. Executive management has an important role in implementing and managing the radiation safety program. DHFS expects executive management to be knowledgeable of the program.

Due to the various structures of different organizations, DHFS recognizes that executive management may need to delegate certain responsibilities to other managers for the day-to-day oversight of the program. For example, a large company may have several licenses issued to it for different facilities or for different activities. In this case, a company may choose to establish a senior level manager with responsibility for all of the licenses issued to that company, with the day-to-day responsibility for each license designated to the facility senior manager or program area senior manager. There are numerous ways in which an applicant may wish to structure its management oversight to meet the needs of the organization. However, there must still be one level of management, as the licensee's representative, with ultimate responsibility for the radiation safety program.

In a Type A broad scope program, executive management or her/his delegate is a vital member of the RSC and should attend Committee meetings. In all licensed programs, executive management should be knowledgeable of the results of periodic audits and the annual review of the licensed program, to ensure all activities are in compliance with regulatory requirements and the conditions of the license, and that activities are being conducted in a safe manner. Annual reviews and audits are discussed in more detail in **Item 12, 'Audit Program'**, of this guidance document.

The licensee should consider several factors when selecting executive management for the radiation safety program. This individual represents the highest level of facility management and has the authority to delegate resources for the program and appropriate funds in a timely manner. This individual must be available to facilitate effective and immediate action on behalf of management, the RSC (for Type A broad scope programs), and the RSO, particularly in the event of an emergency. Executive management must have the authority to make prompt decisions without having to consult with higher management officials, including the authority to take whatever action is necessary to ensure that all radiation safety practices are in accordance with the rules and conditions of the license.

Executive management is involved in selecting the chairperson and members of the RSC (for Type A broad scope) and the RSO (for Type A and Type B broad scope), and defines the role, duties and responsibilities of each. Executive management should support the RSC and the RSO, creating an atmosphere of cooperation and professionalism such that individuals feel comfortable raising radiation safety concerns. Authority will be enhanced if authorized users clearly understand that there is strong management support for, and participation in, the licensed program. Many problems can be avoided if management takes proactive steps before radiation safety problems escalate. Individuals should understand management's expectations regarding internal enforcement of program requirements and the consequences for non-compliance.

NRC NUREG-1516, "Management of Radioactive Material Safety Programs at Medical Facilities," Chapter 1, describes the role of executive management at medical facilities, but it also contains information pertinent to all broad scope programs.

Response from Applicant:

Item 5. Executive Management (Check box and provide the information requested)

We will describe and provide administrative controls and provisions relating to organization, management and management review necessary to assure safe operations. We will also provide an organizational chart describing the management structure, reporting paths, and the flow of authority between executive management, the Radiation Safety Committee (for Type A Broad Scope), and the Radiation Safety Officer (for Type A and Type B broad scope).

Item 6: Radiation Safety Committee (RSC)

Rule: HFS 157.13(3)(c)

Criteria: Type A broad scope licensees must establish a Radiation Safety Committee (RSC), which works with executive management and the Radiation Safety Officer (RSO) in implementing the radiation safety program. Type B and Type C broad scope licensees are not required to establish an RSC.

Discussion: An applicant for a Type A broad scope license must establish a RSC pursuant to HFS 157.13(3)(c). The RSC works with executive management and the RSO in implementing the radiation safety program, and will be involved in establishing policies and procedures for managing the radiation

safety program. The RSC, through the executive management, must have the authority and flexibility necessary so that it may effectively fulfill its role in managing the radiation safety program.

The RSC for a Type A broad scope program is composed of such persons as the RSO, executive management, and persons trained and experienced in the safe use of radioactive materials. Each area of use under the license should be represented on the RSC.

A chairperson for the committee should be selected. There are several factors to consider when selecting a chairperson for the RSC. An individual with a knowledge of radiation safety issues, good leadership abilities, the authority and credibility by virtue of their position within the facility, and a desire to serve as chairperson will facilitate the effectiveness of the RSC. Additionally, the individual chosen as the chairperson must have the time to devote to the position in addition to other responsibilities he or she might have within the facility. Executive management should delegate a level of authority to the position so that the chairperson is effective. In general, the RSO should not be appointed as the chairperson of the Committee, since the RSO is responsible for the day-to-day operation of the radiation safety program and may be too closely involved with the licensed activities to be objective.

The RSC should establish a quorum for RSC meetings. A quorum consisting of the chairperson of the committee (or his/her designee), the RSO, the executive management (or his/her alternate), a representative from each area of use from which specific issues will be discussed, and any other member whose field of expertise is necessary for the discussion is considered acceptable.

The meeting frequency for RSC meetings for broad scope programs is not specified in *HFS 157.13(3)*. The RSC should meet as often as needed to ensure the radiation safety program is operating in compliance with the license, established procedures and the rule. For most programs, quarterly RSC meetings are needed to adequately oversee the program.

The RSC should maintain minutes of its meetings. The minutes should include the date of the meeting, the members present and absent to demonstrate a quorum was present, a summary of the discussions, recommendations and the results of votes. The RSC should also document its review of new users, uses, and program changes. The minutes should also include information related to the ALARA program reviews and the annual audit review.

Duties and Responsibilities

The committee is responsible for reviewing personnel dosimetry data, discussing the results of required radiation surveys, and any significant incidents, including spills, contamination, medical events, etc. The RSC is also required to review the program for maintaining doses ALARA and providing any necessary recommendations to ensure doses are ALARA. The overall compliance status for authorized users should be thoroughly reviewed. The RSC, working with the executive management, shares responsibility with the RSO for conducting periodic audits of the radiation safety program. Additionally, the Committee reviews any consultant's audit findings and acts upon those findings. The RSC also reviews the results of the annual audit of the radiation safety program. Possible trends should be analyzed, and suggestions for timely and corrective action should be made. Problems should be clearly defined and reviewed in the future as open items. An assessment of the effectiveness of corrective actions is also helpful in deterring or eliminating future problems and violations.

One of the primary responsibilities of the RSC for a broad scope program is to evaluate new users and new uses of radioactive material. The RSC needs to consider all available information in making decisions. This includes evaluating the training and experience of applicants who request authorization to use radioactive material at the facility, using criteria developed by the RSC. The RSC members should be aware of the regulatory training and experience criteria that apply to each type of use at their institution. For example, **Chapter HFS 157 Subchapter VI, 'Medical Use of Radioactive Material'** contains the training and experience required for authorized users in medical programs. The criteria developed by the committee should include such things as the requester's training and experience, the proposed facilities, the protocol for using radioactive material to ensure that all procedures are in accordance with good radiation safety practices, and waste disposal.

For Type A broad scope licensees or applicants for a Type A broad scope license who desire the flexibility to make certain program changes and changes to certain procedures as discussed in the 'Purpose of Guide', the RSC, along with executive management and the RSO, will review and approve program and procedural changes in accordance with criteria developed and approved by the RSC. The criteria for reviewing and approving such changes should include provisions for training staff before implementing new procedures and ensure that the proposed changes will not degrade the effectiveness of

the currently approved program. Additionally, the audit program should include an evaluation process that will assure that changes have been properly implemented by the staff and will determine the effectiveness of changes made in achieving program goals.

NRC NUREG-1516, "Management of Radioactive Material Safety Programs at Medical Facilities," Chapter 2, describes the role of the radiation safety committee at medical facilities, but contains information pertinent to all broad scope programs.

For medical broad scope programs, the requirements of **Chapter HFS 157 Subchapter VI**, 'Medical Use of **Radioactive Material'** must be met. Broad scope licensees should review other base WISREGs that may apply to their licensed program, such as **WISREG**, **Volume 9**, "Guidance For Medical Use of Radioactive Material", for licensees who possess radioactive material for medical use.

Response from Applicant:

| Iter | Item 6 Radiation Safety Committee (RSC) (Check all that apply and provide the information requested) | |
|------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|
| | A description of the duties and responsibilities of the RSC is attached. | |
| | AND | |
| | A description of the criteria used for selecting members of the RSC, including members and the number of members constituting a quorum is attached. | |
| | NOTE : Members should be indicated by position title, rather than by name. The chairperson should be identified by name, with training and experience submitted. | |
| | AND | |
| | A description of the criteria used by the RSC and RSO for approving users and new uses is attached | |

In addition, applicants for a Type A broad scope license who are requesting the flexibility to make some program changes and revise some procedures previously approved by DHFS without amendment of the license should submit the following:

- A description of the duties and responsibilities of the RSC, including:
 - -review and approval of permitted program and procedural changes prior to implementation;
 - -implementation of program and procedural changes;
 - -audit of licensed operations to determine compliance; and
 - -taking appropriate actions when noncompliance is identified, including analysis of the cause, corrective actions, and actions to prevent recurrence.

A description of the process for procedure and program review and approval, including
documentation of the specific change. At a minimum, documentation shall state the reason for the
change and summarize the radiation safety matters that were considered prior to approval of the
change.

Item 7: Radiation Safety Officer (RSO)

Rule: HFS 157.13(2); HFS 157.05(4); HFS 157.13(2); HFS 157.05(4)

Criteria: Type A and Type B broad scope licensees must have a Radiation Safety Officer (RSO) who is qualified by training and experience in radiation protection, and who is available for advice and assistance on radiological safety matters. The RSO's training and experience must include the types and quantities of licensed material to be authorized on the license. While the rule does not require Type C broad scope licensees to have an RSO, *HFS* 157.13(3)(c) requires that the licensee establish administrative controls and provisions relating to procurement of radioactive material, procedures, recordkeeping, material control and accounting, and management review to assure safe operations. Type C broad scope licensee management should appoint someone responsible for the day-to-day operation of the radiation safety program, such as an RSO.

Discussion: Each Type A and Type B program must appoint an RSO who is responsible for radiation safety and compliance with the rules for the use of radioactive material. Each Type C broad scope program should appoint an individual who is responsible for the day-to-day operation of the radiation safety program. In a Type A broad scope license the RSO is a member of the RSC and works closely with the RSC and executive management in implementing the radiation safety program. The RSO must ensure that radiation safety activities are being performed safely according to approved policies and procedures, and that all regulatory requirements are met. The RSO should have full access to all activities involving the use of radioactive material and the authority to terminate any activity, in which health and safety appear to be compromised without consulting with executive management or the RSC, if required. The applicant should submit a "Radiation Safety Officer Delegation of Authority" signed by executive management. **Appendix J** contains a sample "Delegation of Authority" that is acceptable to DHFS.

In a Type A broad scope licensed program, the RSO typically performs a preliminary review of proposed new uses and users, prior to formally discussing the proposal with the RSC. The RSC grants the formal approval of new users and uses in a Type A broad scope license. The task of reviewing and approving proposed uses and users in a Type B broad scope licensed program is the responsibility of the RSO. In a Type C broad scope program, individuals are qualified as users if they meet the training and experience criteria described in *HFS* 157.13(3)(e). While no licensee Committee or individual is required by the rule to make the determination that an individual is qualified to use the material possessed under the Type C broad scope license, or that a particular use of radioactive material is safe, licensee management is ultimately responsible for assuring safe operations.

The RSO performs audits of all areas of use and individuals who are authorized to use radioactive material to ensure work is done in accordance with the license, the rule, and user permit conditions. Specific duties and responsibilities of the RSO include:

- Monitoring and surveys of all areas in which radioactive material is used
- Oversight of ordering, receipt, surveys, and delivery of radioactive material
- Packaging, labeling, surveys, etc., of all shipments of radioactive material leaving the institution
- Personnel monitoring program, including determining the need for and evaluating bioassays,
 monitoring personnel exposure records, and developing corrective actions for those exposures
 approaching maximum permissible limits
- Training of all personnel
- Waste disposal program
- Inventory and leak tests of sealed sources
- Decontamination
- Investigating any incidents and responding to any emergencies
- Maintaining all required records.

The responsibilities of the RSO may not be transferred to other individuals. Many tasks and duties associated with managing the program may be assigned or delegated to other qualified individuals; however, the responsibility for these tasks and duties is with the RSO. DHFS does recognize that a qualified individual will have to fill in for the RSO when the RSO will be away for short periods of time for professional conferences, vacation, or illness. However, this should not occur for extended or

indefinite periods of time. Consideration should also be given to how this individual would be contacted in the event of an emergency.

When selecting an RSO, the applicant should keep in mind the duties and responsibilities of the position, select an individual who is qualified to serve as the RSO. The RSO will need a basic technical knowledge sufficient to understand, in general, the majority of the work being done with radioactive materials under his or her responsibility. DHFS recognizes that an RSO cannot be an expert in all areas that might be involved in a broad scope program. The RSO should be qualified by training and experience to perform the duties required for the position. Executive management should ensure that enough time is allocated to the individual selected as the RSO to carry out the responsibilities of the position.

The applicant should review the Radiation Safety Officer guidance provided in the base WISREG corresponding to the particular type of licensed program. For example, WISREG-1556, Volume 7, "Guidance For Academic, Research and Development, and Other Licenses of Limited Scope," contains guidance that is appropriate for broad scope licensees who are involved in research and development.

The applicant should also be aware of specific regulatory requirements for the RSO that may apply to their licensed program. For example, **Chapter HFS 157 Subchapter VI, 'Medical Use of Radioactive Material'** contains specific requirements for an RSO in a medical program. However, an individual who qualifies as a medical RSO is not necessarily qualified to be RSO in a broad scope program.

Chapters 3 and 4 of NRC NUREG 1516, "Management of Radioactive Material Safety Programs at Medical Facilities," describes the role of the RSO and selection of the RSO at medical facilities but also contains information pertinent to all broad scope programs.

Response from Applicant:

| Ite | Item 7 Radiation Safety Officer (RSO) (Check all that apply) | |
|-----|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|
| | The name of the proposed RSO and other potential designees who will be responsible for ensuring that the licensee's radiation safety program is implemented in accordance with approved procedures. | |
| | Name: Telephone Number (Include area code): | |
| | AND | |
| | A delegation of authority letter is included which authorizes the RSO to submit license amendment requests. | |
| ı | AND | |
| | We will provide information demonstrating that the proposed RSO is qualified by training and experience. | |
| | AND | |
| | We will provide a statement delineating the RSO's duties and responsibilities, signed by the licensee's executive management. | |
| ı | FOR TYPE C BROAD SCOPE | |
| | We will submit the name of the person who will serve as the individual responsible for the day-to-day operation of the radiation safety program. | |

Note: Applicants should provide specific information about the proposed RSO's training and experience which is relative to the licensed material requested in the application. Applicants should not submit extraneous information such as unrelated lists of publications, research grants, committee and society memberships, etc. This only serves to slow down the review process.

It is important to notify DHFS, as soon as possible, typically within 30 days, of changes in the designation of the RSO. The name and qualifications of the replacement RSO must be submitted to DHFS as part of an amendment request. Applicants should review the rules for specific program areas, such as medical uses, that have specific requirements regarding changes in the RSO.

Item 8: Training for Individuals Working In or Frequenting Restricted Areas (Occupationally exposed individuals and ancillary personnel.)

Rule: HFS 157. 88(1); 157.88(2); 157.88(3); 157.13(3); 157.13(9)(b) and 157.13(10)

Criteria: Before beginning work with or in the vicinity of licensed material, all individuals who are likely to receive an occupational dose in excess of 1 mSv (100 mrem) in a year must receive radiation

safety training commensurate with their assigned duties and specific to the licensee's radiation safety program. Each individual should also receive periodic refresher training.

Discussion: *HFS* 157. 88(2) describes the training that licensees are required to provide individuals who, in the course of their employment, are likely to receive in a year an occupational dose in excess of 1 mSv (100 mrem). *HFS* 157.88(2) requires that the licensee, in determining which individuals are subject to the training requirements of *HFS* 157.88(3), consider assigned activities during both normal and abnormal situations involving exposure to radiation and/or radioactive material that can reasonably be expected to occur during the life of a licensed facility. While many licensees can demonstrate that it is not likely during a normal situation for a laboratory worker, manufacturing technician, hospital technologist, or environmental services worker at their facility to receive in a year an occupational dose in excess of 1 mSv (100 mrem), these individuals and others could reasonably be expected to receive this level of exposure during abnormal situations (e.g., radioactive material left unsecured, a contamination event, or improper disposal of radioactive material in the regular trash) or, by their actions, cause others to receive this level of exposure. Untrained workers represent a potential hazard to themselves, other individuals, and property.

Licensees should not assume that safety instruction has been adequately covered by prior employment or academic training. Practical, site-specific training should be provided for all individuals prior to beginning work with or in the vicinity of licensed material. Periodic refresher training should also be provided. Topics covered should, at a minimum, include those described in *HFS 157.88(2)*. The training may take any form. Many licensees utilize videotapes or interactive on line or off line computer programs to provide training. The licensee should determine whether the training succeeded in conveying the desired information and adjust the training program as necessary. The person conducting the training should be a qualified individual who is familiar with the licensee's program.

Retraining should be performed whenever there is a change in duties or the work environment and at a frequency sufficient to ensure that all staff are adequately trained.

Applicants should review the model training program described in the appropriate base WISREG corresponding to the particular type of licensed program. For example, WISREG-1556, Volume 7 'Guidance for Academic, Research and Development, and Other Licenses of Limited Scope', describes a

training program that is acceptable to DHFS for licensees who are involved in research and development, and WISREG-1556 Volume 9 *'Guidance for Medical Use of Radioactive Material'* describes a training program that is acceptable to DHFS for licensees who possess radioactive material for medical use.

The applicant should also be aware of additional specific training requirements that may apply to their licensed program. For example, **Chapter HFS 157 Subchapter VI**, 'Medical Use of Radioactive Material' contains specific requirements for the training of individuals who will work under the supervision of medical authorized users.

Response from Applicant:

Item 8 Training For Individuals Working In Or Frequenting Restricted Areas (Occupationally exposed individuals and ancillary personnel) (Check Box)

A description of the radiation safety training program, including topics covered, groups of workers, assessment of training, qualifications of instructors and the method and frequency of training is attached.

Note: If you are a Type A broad scope licensee or applicant, and you want the flexibility to revise your radiation safety training program without amendment of the license as discussed in the section titled **'Purpose of this Guide'** and **Item 6**, Radiation Safety Committee, describe the process that will be used to revise and implement your submitted program.

Item 9: Radioactive Material

Unsealed and/or Sealed Radioactive Material

Rule: HFS 157.09(2)(b); 157.13(1); HFS 157 Appendixes P & Q; 157.13(2); 157.13(3)(b); 157.13(3)(c); 157.13(3)(d); 157.13(3)(e); and 157.13(3)(f)

Criteria: An application for a license will be approved if the requirements of *HFS 157.13(1); HFS 157 Appendixes P & Q; 157.13(2); 157.13(3)(b); 157.13(3)(c); 157.13(3)(d); 157.13(3)(e); and 157.13(3)(f)* are met.

Discussion: Applicants for a Type A broad scope license typically request any form of radioactive material with atomic numbers from 1 through 83. The applicant should state the maximum quantity of

each radionuclide to be possessed at any one time and the total cumulative quantity for all radionuclides. When establishing individual radionuclide and total cumulative quantities, all materials possessed under the license should be included (i.e., materials received awaiting use, materials in use/process, and those categorized as waste awaiting disposal). The maximum quantity for each individual radionuclide and total cumulative possession should be commensurate with the applicant's needs, facilities, procedures, and demonstrated experience/capability.

If certain individual unsealed radionuclides will be needed in much larger quantities than described in the atomic number 1-83 request, they should be listed separately rather than increasing the possession limit for all radionuclides. Similarly, if it is known that certain radionuclides are needed only in smaller quantities, they should be listed separately.

A separate listing should also be submitted for sealed sources needed in quantities larger than that described in the atomic number 1-83 request (e.g., self-contained irradiators, instrument calibrators, sealed sources used for medical therapy, portable and non-portable gauging devices, etc.). Applicants must provide the manufacturer's name and model number for each requested sealed source and device so that DHFS can verify that they have been evaluated in a Sealed Source and Device (SSD) Registration Certificate or specifically approved on a license. Before the formalization of the SSD registration process, some older sources or devices may have been specifically approved on a license. Licensees can continue to use those sources and devices specifically listed on their licenses. Sealed sources or devices containing sealed sources that are intended for use solely under broad scope licenses and are not transferred to another licensee need not be evaluated by DHFS prior to use if: (1) the licensee is authorized to possess the requested quantity of radioactive material in unsealed form; and (2) the licensee performs its own safety evaluation in accordance with the administrative procedures required by *HFS 157.13(3)* as appropriate. For example, a broad scope licensee who is authorized to possess and use any form of iridium-192 or cobalt-60 in the fabrication of sources and devices for industrial radiography may use the fabricated sources and devices to conduct its own licensed activities without first submitting the sources and devices to NRC or an Agreement State for evaluation and registration.

If needed, an applicant for a Type A broad scope license may request authorization to possess radioactive materials with atomic numbers greater than 83 (e.g., atomic numbers 84 to 96). For this request, the applicant should state the maximum quantity of each radionuclide to be possessed at any one time and the

total cumulative quantity for all radionuclides. Note that authorization to possess radioactive materials with atomic numbers 84 through 96 does not authorize the possession of uranium, thorium, or plutonium classified as either source material or special nuclear material. Licensees may request authorization for source material and special nuclear material when use of these materials is directly related to the use of radioactive material under the broad scope license (e.g. laboratory-scale research and development or the use of depleted uranium as shielding).

Applicants should submit separate applications for the use of source and special nuclear materials for purposes not directly related to the use of radioactive material under the broad scope license (e.g., subcritical assemblies and nuclear pacemakers).

A safety evaluation of sealed sources and devices is performed by NRC or an Agreement State before authorizing a manufacturer (or distributor) to distribute them to specific licensees. The safety evaluation is documented in an SSD Registration Certificate. Information on SSD registration certificates is available on the NRC's web site at http://www.hsrd.ornl.gov/nrc and may also be obtained by contacting the Registration Assistant by calling NRC's toll free number, (800) 368-5642, Extension 415-8140. For additional guidance relating to sealed sources and devices, see also NUREG-1556, Vol. 3., "Applications for Sealed Source and Device Evaluation and Registration."

Possession requests should be categorized into general areas of use, e.g., research and development activities, routine gauging activities, self-shielded irradiators, instrument calibrators, and medical applications.

Applicants for Type A broad scope license should review the requirements for financial assurance and decommissioning before specifying possession limits for radioisotopes with a half-life greater than 120 days. These requirements are discussed in **Item 10 'Financial Assurance and Recordkeeping for Decommissioning'** of this WISREG.

Licensees who possess radioactive materials in excess of the quantities listed in **Chapter HFS 157 'Radiation Protection' Appendix P** must provide with the application either of the following:

- An evaluation showing that the maximum off-site dose due to a release of radioactive materials would not exceed 0.01 Sv (1 rem) effective dose equivalent or 0.05 Sv (5 rem) to the thyroid; or
- An emergency response plan for responding to the release in accordance with the criteria listed in *HFS 157.13(10)*, Chapter HFS 157 'Radiation Protection' Appendixes P and Q.

If you are required to establish an emergency plan, guidance is provided in NRC Regulatory Guide 3.67, "Standard Format and Content for Emergency Plans for Fuel Cycle and Materials Facilities," dated January 1992, and NRC Policy and Guidance Directive 84-14, Revision 1, "Standard Review Plan for Emergency Plans for Fuel Cycle and Materials Licenses". NRC NUREG 1140, "A Regulatory Analysis on Emergency Preparedness for Fuel Cycle and Other Radioactive Material Licensees, Final Report," dated January 1988, also contains valuable information.

Applicants for a Type B or Type C broad scope license may request any chemical or physical form of radioactive material specified in **Chapter HFS 157 'Radiation Protection'**, **Appendix C**. The possession limit for a Type B broad scope license, if only one radionuclide is possessed, is the quantity specified for that radionuclide in **Chapter HFS 157 'Radiation Protection'**, **Appendix C**, **Column I**. If two or more radionuclides are possessed, the possession limit is determined as follows. For each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in **Chapter HFS 157 'Radiation Protection'**, **Appendix C**, **Column I**, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity. The possession limit for a Type C broad scope license, if only one radionuclide is possessed, is the quantity specified for that radionuclide in **Chapter HFS 157 'Radiation Protection'**, **Appendix C**, **Column II**. If two or more radionuclides are possessed, the sum of the ratios, determined in the same manner as discussed above, for all radionuclides possessed under the license shall not exceed unity.

Type B and Type C broad scope licensees who require materials not specified in **Chapter HFS 157**'Radiation Protection', Appendix C will need to: (1) develop Type A broad scope programs; or (2) carry these additional materials under a separate specific license of limited scope. The latter option would require that the licensee review the base WISREG related to the specific use of this material and submit the information required by the license reviewer as described in that document. For example, applicants who require materials not specified in Appendix A for purposes of research and development should review WISREG-1556, Volume 7, "Guidance For Academic, Research and Development, and Other Licenses of Limited Scope", and submit the information described therein.

Type B licensees who require quantities of material in excess of that permitted by *HFS 157.13(3)(b) 2*, will need to: (1) develop a Type A broad scope program; or (2) carry these additional quantities under a

separate specific license of limited scope, as described in the previous paragraph. Type C licensees who require quantities of material in excess of that permitted by *HFS 157.13(3)(b) 3*, will need to: (1) develop, as appropriate, a Type A or Type B broad scope program; or (2) carry these additional materials under a separate specific license of limited scope.

Applicants for broad scope license may consider limiting their possession of isotopes described in **HFS 157 Appendix C** with half lives greater than 120 days below that amount permitted by *HFS* 157.13(3)(b), to avoid being required to submit certification of financial assurance or a decommissioning funding plan. See section titled 'Financial Assurance and Recordkeeping for Decommissioning' of this document for further discussion.

Response from Applicant:

| Item 9 Radioactive Material (Attach additional pages if necessary) | | | | |
|--------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|-------------------------------|-----------------|
| | Atomic Number 1-83 Request | | | |
| | ☐ We request authorization for radionuclides with Atomic Number 1-83 in any form with a maximum quantity of per radionuclide and maximum possession limit. | | | f per |
| | Intended uses include: ☐ non-human research and development activities.☐ animal studies.☐ other (list general category of use) | | | |
| Radionuclides in Larger or Smaller Quantities than Atomic Number 1-83 Request - Unsealed sources of radioactive material | | | | |
| Radioisotope | | | | |
| Chemical/Physical Form | | | | |
| Maximum Possession Limit | | | | |
| Proposed use of Radioactive material | | | | |
| Radionuclides in L | arger Quantities than At | tomic Number 1-83 Reques | st - Sealed sources of radioa | active material |
| Radioisotope | | | | |
| Sealed Source Manufacturer or Distributor and Model Number | | | | |
| Device Manufacturer or Distributor and Model Number | | | | |
| Sealed Source Device Registration Sheet Number | | | | |
| Maximum Possession Limit | | | | |
| Proposed Use of Radioactive Material | | | | |
| | Note : If applicable, an evaluation or an emergency response plan is included for radionuclide(s) in excess of the amounts listed in Chapter HFS 157 'Radiation Protection' Appendix P. | | | |

Possession requests should be categorized into general areas of use, e.g., non-human research and development activities, animal studies and others (specify).

Licensees who possess radioactive materials in excess of the quantities listed in **Chapter HFS 157 'Radiation Protection'**; **Appendix P** must provide with the application either of the following:

- An evaluation showing that the maximum off-site dose due to a release of radioactive materials would not exceed 0.01 Sv (1 rem) effective dose equivalent or 0.05 Sv (5 rem) to the thyroid; or
- An emergency response plan for responding to the release in accordance with the criteria listed in $HFS\ 157.13(1)(g)$.

ITEM 10: Financial Assurance and Recordkeeping for Decommissioning

Rule: HFS 157.131; HFS 157 Appendixes P & Q; HFS 157.13(9)(b); HFS 157.13(10); HFS 157.15; HFS 157.13(11); HFS 157.06(1); HFS 157.13(18); and HFS 157.31

Criteria: Pursuant to the rule requirements described above, the licensee must do the following:

- Notify DHFS, in writing, within 30 days of:
 - Decision to permanently discontinue all activities involving materials authorized under the license.
- Notify DHFS, in writing, within 60 days of:
 - The expiration of its license;
 - A decision to permanently cease licensed activity at the entire site or in any separate building or outdoor area if it contains residual radioactivity making it unsuitable for release according to DHFS requirements;
 - No principal activities have been conducted at the entire site under the license for a period of 24 months;
 - No principal activities have been conducted for a period of 24 months in any separate building or outdoor area if it contains residual radioactivity making it unsuitable for release according to DHFS requirements.
- Submit a decommissioning plan, if required by *HFS 157.13(11)(f)*;
- Conduct decommissioning, as required by HFS 157.13(11)(i) and HFS 157.13(11)(l); and
- Submit to DHFS, a completed DPH Form 45007 'Certificate of Disposition of Materials' and demonstrate that the premises are suitable for release for unrestricted use (e.g. results of final survey).

• Before a license is terminated, send the records important to decommissioning to DHFS. If licensed activities are transferred or assigned in accordance with *HFS 157.13(5)(c) 2*, transfer records important to decommissioning to the new licensee.

Note: The licensee's obligations are to undertake the necessary decommissioning activities, to submit DPH Form 45007 'Certificate of Disposition of Materials', and to perform any other actions as summarized in the "Criteria."

A licensee authorized to possess licensed material in excess of the limits specified in *HFS 157.15* and *HFS 157.13(10)(b)* must meet the requirements for decommissioning financial assurance. All licensees are required to maintain records of information important to the decommissioning of the facility in an identified location until the site, or any area, is released for unrestricted use. Licensees must transfer these records either to the new licensee, when licensed activities are transferred or assigned, or to DHFS when the license is terminated.

Discussion: DHFS wants to ensure that decommissioning will be carried out with minimum impact on public and occupational health and safety and the environment. There are two parts to the rule: financial assurance that applies to some licensees and recordkeeping that applies to all licensees.

DHFS decommissioning financial assurance rules are designed to provide reasonable assurance that the decommissioning of licensed facilities will be accomplished in a safe and timely manner and that licensees will provide adequate funds to cover all costs associated with decommissioning. These requirements, if applicable, specify that a licensee either set aside funds for decommissioning activities or provide a guarantee that funds will be available. Applicants are required to provide financial assurance when the possession of radioactive material of half-life (T1/2) greater than 120 days exceeds certain limits. Criteria for determining whether an applicant is required to submit a Decommissioning Funding Plan (DFP) or has an option of submitting either a DFP or a Certification of Financial Assurance are stated in *HFS 157.15* and *HFS 157.13(10)(b)*. A DFP contains a site-specific cost estimate and a certification of financial assurance. A Certification of Financial Assurance includes a certification that the licensee has provided the required financial assurance and an acceptable financial assurance instrument.

Acceptable financial assurance includes prepayment options (trusts, escrow accounts, government funds, certificates of deposit or deposits of government securities); surety, insurance, or other guarantee methods (letters of credit, surety bonds, lines of credit, parent company guarantees, insurance policies), and statements of intent for Government entities. Criteria for parent company guarantees and self-guarantees can be found in *HFS 157.15* and Chapter *HFS 157 ' Radiation Protection'*, *Appendix P*.

NRC Regulatory Guide (RG) 3.66, "Standard Format and Content of Financial Assurance Mechanisms Required for Decommissioning Under 10 CFR Parts 30, 40, 70, and 72," dated June 1990, provides guidance acceptable to DHFS staff on the information to be provided for establishing financial assurance for decommissioning and a standard format for presenting the information. A revision to RG 3.66 will incorporate new guidance related to self-guarantees. RG 3.66 also describes the information required to be submitted for a DFP. NRC NUREG-1337, Revision 1, "Standard Review Plan for the Review of Financial Assurance Mechanisms for Decommissioning Under 10 CFR Parts 30, 40, 70, and 72," dated August 1989, also provides guidance for decommissioning financial assurance reviews.

The requirements for maintaining records important to decommissioning, including the type of information required, are stated in *HFS 157.15*. All licensees are required to maintain these records in an identified location until the site is released for unrestricted use. Careful recordkeeping of radionuclides used, including form, amount, and area used, will facilitate area release and license termination. In the event that the licensed activities are transferred to another person or entity, these records shall be transferred to the new licensee when the transfer of the licensed activities takes place. The new licensee is responsible for maintaining these records until the license is terminated. When the license is terminated, these records must be transferred to DHFS.



Figure 2 - Types of records that must be maintained for decommissioning.

HFS 157.15, Requirements for Disposition of Records Important to Decommissioning

• Before licensed activities are transferred or assigned according to HFS 157.13(9)(b) and HFS 157.13(10), transfer to the new licensee.

OR

Before the license is terminated, transfer records to DHFS.

Response from Applicant:

Item 10 Financial Assurance And Recordkeeping For Decommissioning (Check box)

We will provide a decommissioning funding plan or a certification of financial assurance as required in s. HFS 157.15 (Attached if required)

Item 11: FACILITIES AND EQUIPMENT

Rule: HFS 157.21; 157.13(2)(b); 157.13(2); 157.13(9)(b) 157.13(10); 157.15; 157.13(3)(c); 157.13(3)(d); and 157.13(3)(e)

Criteria: Facilities and equipment must be adequate to protect health and minimize danger to life or property. They must minimize the possibility of contamination and keep exposures to workers and the public ALARA.

Discussion: Applicants for all broad scope licenses need to demonstrate that their facilities and equipment provide sufficient engineering controls and barriers to protect the health and safety of the public and its employees, keep exposures to radiation and radioactive materials ALARA, and minimize the danger to life and property from the types and quantities of radioactive materials to be used. Facilities and equipment designed to control exposure can range from a vial that contains licensed material, to buildings, fences, or exclusion areas that are between the source and the maximally exposed member of the public. These facilities not only reduce the exposure from the source but may also limit access to the source. The licensee should list and describe these facilities for the following purposes:

- To show compliance with **Chapter HFS 157 'Radiation Protection'**
- To demonstrate the use of the material will be within the ALARA concept
- To meet emergency response requirements.

Licensees should consider controlling exposures through available engineering options, as well as through limiting the releases of effluents to the environment. The licensee should describe all facilities and equipment essential to achieving these goals. The licensee will also need to describe the criteria that will be used by the RSC and/or RSO, as appropriate, to review and approve of proposed facilities. Facilities and equipment used for special applications where the impact upon workers or the public could be significant if radioactive material were released accidentally need to be specifically described. These would include, for example, room irradiators, specialized iodination/tritiation facilities, alpha laboratories, radioactive waste processing facilities (including incinerators, compactors, liquid reclamation processors, etc.), radioactive waste storage facilities (including decay-in-storage locations), individual laboratories processing 3.7 gigabecquerels (GBq) (100 millicuries) or more of radioactive material per experiment or process, nuclear pharmacies, specially designed therapy rooms, and sealed source storage areas.

Significant modifications affecting facilities and equipment should have prior RSO review and RSC approval before commencement of such modifications.

Also, note that if radioactive material will be used in or on animals, a description of the animal handling and housing facilities will need to be discussed. **Appendix H** of WISREG-1556 Volume 7, "Guidance For Academic, Research and Development, and Other Licenses of Limited Scope", provides guidance on the information that should be addressed concerning the use of radioactive material in animals.

In your discussion of the criteria used to evaluate your facilities and equipment, you should include a discussion on how a laboratory or facility classification scheme relates to toxicity and quantity of radioactive material and your facility and equipment requirements. For example, the International Atomic Energy Agency (IAEA), as well as other health physics and industrial hygiene professional organizations, has developed classification schemes used in assessing minimum needs (e.g., equipment and facilities, user training, personnel monitoring, surveys) that consider the hazard and quantity of radioactive materials to be used (IAEA Safety Standard, Safety Series No. 1, "Safe Handling of Radionuclides, 1973 Edition.") Applicants may consider the development of such a classification scheme since it can be correlated with all aspects of the radiation safety program. Each applicant's scheme should be based upon the types and quantities of radioactive material anticipated to be used. The criteria used to develop the classification scheme should be provided to each RSC member for use when evaluating requests to use licensed materials.

Appendix K of this guide provides the radionuclide toxicity and laboratory classification information from IAEA, which is acceptable to the DHFS staff. This table is not all-inclusive and is meant as an example only. Based on chemical/physical form, need and quantities, your classification scheme may differ from that of the IAEA excerpt. Your application will need to describe the minimum facilities and equipment requirements for each laboratory classification.

Appendix L of this guide provides additional guidance regarding facilities and equipment used to handle radioactive materials in a laboratory setting.

Response from Applicant:

Item 11 Facilities And Equipment (Check all that apply and attach the requested information.)

A description of the criteria used by the RSC (Type A) or RSO (Type B), as appropriate, that will be used to review and approve facilities and equipment (research laboratories, iodination facilities, waste storage facilities, survey and counting equipment, etc.) is attached.

NOTE: See Appendices K and L of WISREG "Guidance for Licenses of Broad Scope" for guidance.

Note: For special application facilities you will need to specify their locations (i.e. buildings and room numbers) and special considerations that your RSC and/or RSO will use in authorizing radioactive material use. Also, describe your procedures for control, review, and approval of significant facilities or equipment modifications.

Item 12 Radiation Safety Program

Item 12.1: Audit Program

Rule: HFS 157.13(3)(c); 157.13(3)(d); 157.13(3)(e); 157.21; and 157.31(2)

Criteria: Applicants for Type A, Type B, and Type C broad scope licenses are required by *HFS* 157.13(3)(c), 157.13(3)(d), and 157.13(3)(e) respectively, to establish administrative controls and provisions relating to management review necessary to ensure safe operations. *HFS* 157.21 requires the licensee to review the radiation program content and implementation, periodically (at least annually). Licensees are required by *HFS* 157.31(2) to maintain records of the radiation protection program, including, (1) the provisions of the program; and (2) audits and other reviews of the program content and implementation.

Discussion:

Management and Radiation Safety Committee Audits

The application for a Type A, B, or C broad scope license should discuss executive management oversight of the licensed program and the mechanisms they will use to ensure that they are aware of **Chapter HFS**157 'Radiation Protection', the provisions of the license, and the compliance status of the institution's

license program. This oversight may include independent audits of the program, frequent meetings with the RSC and/or RSO as appropriate and periodic tours of selected facility areas.

In a Type A broad scope program, the RSC assists executive management in performing this oversight function. Detailed written procedures should be developed and implemented for the operation of the RSC to ensure that appropriate oversight is provided. The RSC should be fully aware of the operations and activities of the Radiation Safety Office. The RSC should conduct periodic interactive management audits and evaluations of the Radiation Safety Program's performance, including: non-conformance reports; corrective action; status reports and audits; incident investigation reports; ALARA program development and implementation; effluent releases; qualification and radiological safety training; and performance of the RSO. Results of the RSC's audit and program reviews should be reported to executive management to allow for timely and aggressive remedial actions sufficient in scope to ensure compliance with **Chapter HFS 157 'Radiation Protection'** and license conditions.

Appendix M of this document contains a sample audit program that is acceptable to DHFS for use in the review of most non-medical broad scope programs.

HFS 157.21 requires the licensee to review the radiation program content and implementation periodically (at least annually). Generally, these audits are conducted at least once every 12 months.

Internal Audits

The application should describe the audit mechanism implemented by the RSO and her or his staff, or other individual who is responsible for the day-to-day operation of the licensed program, to determine user compliance with **Chapter HFS 157 'Radiation Protection'**, the terms and conditions of the DHFS license, the requirements of the RSC or RSO-approved permits (as appropriate), and good health physics practices. The audit program should include routine unannounced inspections of each user's facility and practices to supplement and audit the routine monitoring performed by the user. Facility inspections should include:

- Review of user inventory and survey records
- Evaluation of user and technician training through discussion and observation of work practices

- Performance of independent surveys of user work areas
- Evaluation of compliance with **Chapter HFS 157 'Radiation Protection'**, the conditions of the license, the RSC/RSO permit and safety manual requirements
- Provision for performance-based instruction to users and technical-level staff.

The types and frequencies of monitoring performed by the RSO should be indicated. The intervals of surveys and audits should be frequent enough to ensure close communications and proper surveillance of individual radioactive material users. Applicants should consider developing survey and audit schedules based on activity and use (e.g., high use facilities and users of volatile radioactive materials may be audited weekly or biweekly, intermediate use facilities may be audited monthly, and low-level facilities may be audited quarterly).

If an audit identifies violations of **Chapter HFS 157 'Radiation Protection'**, the licensee should evaluate the safety significance of each violation to set priorities and identify resources to correct these violations. NRC Information Notice (IN) 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," dated May 1, 1996, provides guidance on this subject. Certain identified problems or potential violations may require notification or a report to the DHFS. **Appendix N** of this document describes the more common DHFS reporting requirements. Licensees are encouraged to contact DHFS for guidance if there is any uncertainty regarding a reporting requirement. DHFS routinely reviews licensees' records to verify if appropriate corrective actions were implemented in a timely manner to prevent recurrence. It is in the best interest of the licensee to identify potential violations of regulatory requirements and take necessary steps to correct them. DHFS can exercise discretion and may elect not to cite the licensee for these violations if prompt and effective corrective actions are implemented.

DHFS's emphasis in inspections is for applicants to perform actual observations of work in progress. As a part of their audit programs, applicants should consider performing unannounced audits of radioactive material users to determine if, for example, safe use of radionuclide procedures and emergency procedures are available and are being followed.

Recordkeeping

HFS 157.31(2) requires that licensees maintain records of audits and other reviews of program content and implementation for 3 years from the date of the record. Records of audits should include: date of audit, name of person(s) who conducted the audit, persons contacted by the auditor(s), areas audited, audit findings, corrective actions, and follow-up. These records must be maintained for inspection by DHFS.

Response From Applicant:

| Item 12.1 Audit Program (Check all that apply) | | | |
|------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|--|
| | A description of the mechanisms used by executive management to ensure that adequate oversight of the Broad Scope Radiation Safety program is exercised, is attached. | | |
| | AND | | |
| | A description of the audit mechanism implemented by the RSO to determine user compliance with Chapter HFS 157 'Radiation Protection', the terms and conditions of the DHFS license, the requirements of the RSC (Type A) or RSO-approved permits(Type B) as appropriate, and good health physics practices are attached. | | |
| | NOTE: The applicant is not required to submit its audit program to DHFS for review during the licensing phase. This matter will be examined during an inspection. | | |

Note: If you are a Type A broad scope licensee or applicant, and you want the flexibility to revise your radiation safety audit program without amendment of the license as discussed in the section titled **'Purpose of this Guide'** and **Item 6**, Radiation Safety Committee, describe the process that will be used to revise and implement your submitted audit program.

Item 12.2: Radiation Monitoring Instruments

Rule: HFS 157. 25(1); 157.31(3); 157.13(2); 157.13(3)(c); 157.13(3)(d); 157.13(3)(e); 157.38; 157.45(3); and 157.61(8)

Criteria: Licensees must, pursuant to *HFS 157.25(1)*, possess and periodically calibrate radiation monitoring instruments that are necessary to protect health and minimize danger to life or property.

Discussion: Licensees must possess an adequate number of radiation detection and measurement instruments as necessary and ensure they are calibrated periodically for the radiation being measured. For purposes of this document, survey instruments are defined as any device used to measure the radiological

conditions at a licensed facility. The choice of instrument needs to be appropriate for the type of radiation to be measured and for the type of measurement to be taken (count rate, dose rate, etc.).

The applicant should submit the criteria used in determining what radiation detection and monitoring equipment will be required for each type of use by authorized users and the availability of a sufficient quantity of these instruments to both the radiation safety office and authorized users (e.g., ion-chambers, G-Ms, air samplers, liquid scintillation counters).

DHFS requires that survey instruments used to determine compliance with regulatory requirements be calibrated periodically by the instrument manufacturer or persons specifically authorized by DHFS, the NRC, or another Agreement State. Survey instruments should be calibrated at least annually (every 12 months), unless otherwise specified by the rule or license condition. Licensees seeking authorization to perform their own survey instrument calibrations will need to submit calibration procedures for review. The licensee may wish to review available industry standards for calibration of instruments such as ANSI N323A-1997, "Radiation Protection Instrumentation Test and Calibration, Portable Survey Instruments". Appendix O of this document provides useful information about instrument specifications and sample calibration procedures that are acceptable to DHFS.

Applicants will need to submit their method for assuring that instruments are calibrated at proper frequencies.

Response from Applicant:

| Iter | Item 12.2 Radiation Monitoring Instruments (Check all that apply) | | | |
|------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|--|--|
| | A description of the criteria used by the RSC (Type A) or RSO (Type B), as appropriate, to review and approve radiation monitoring instrumentation to assure that appropriate radiation monitoring equipment will be used during licensed activities is attached. | | | |
| | AND | | | |
| | A description of how the RSC (Type A) or RSO (Type B), as appropriate, will assure that instruments are properly calibrated at prescribed frequencies is attached. | | | |
| | AND ONE OF THE FOLLOWING | | | |
| | Instruments will be calibrated by an organization licensed by DHFS, the NRC or an Agreement State to perform instrument calibrations. | | | |
| | OR | | | |
| | We will follow the procedures for instrument calibrations in Appendix O of WISREG "Guidance for Licenses of Broad Scope." | | | |
| | OR | | | |
| | A description of alternative procedures is provided for ensuring that proper calibration of survey equipment will be performed. (Procedures are attached) | | | |

Note: If you are a Type A broad scope licensee or applicant, and you want the flexibility to revise your radiation monitoring instruments program without amendment of the license as discussed in the section titled **'Purpose of this Guide'** and **Item 6**, Radiation Safety Committee, describe the process that will be used to revise and implement your submitted program.

If you wish to perform instrument calibration as a commercial service, you will need to either amend your existing broad scope license or apply for a new DHFS license authorizing commercial calibration service.

Item 12.3: Material Receipt and Accountability

Rule: HFS 157.25(1); 157.28(1)(a); 157.28(1)(b); 157.29(6); 157.30(1); 157.31(9); 157.32(1); 157.13(9)(b) & (10); 157.15; 157.13(15); 157.06(1); 157.13(18); 157.13(3)(a); 157.13(3)(d); and 157.13(3)(e)

Criteria: Licensees must, pursuant to Chapter HFS 157 'Radiation Protection', Subchapters II and III, develop, implement, and maintain written procedures for all of the following:

- Purchasing and receipt of radioactive material
- Safely receiving and opening packages

• Ensuring control and accountability of licensed material.

The licensee must also maintain records of receipt, utilization, transfer, and disposal of licensed material.

Discussion: Applicants for a broad scope license are required to establish appropriate administrative controls and provisions that are necessary to assure safe operations including procedures to assure the control of procurement and use of radioactive material. Administrative procedures must assure that only authorized individuals receive radioactive materials and that individuals receive only the types and quantities of radioactive material that they are authorized to receive.

Applicants for a broad scope license are strongly encouraged to develop an administrative procedure to control procurement and use of radioactive material that emphasizes centralized purchasing and receipt. DHFS has found centralized purchasing and receipt to be effective in controlling licensed materials entering the licensed institution through normal commercial channels, particularly for larger institutions. Procedures must also be established to control licensed materials obtained outside of the normal channels, e.g., through the loan or transfer of materials without purchase or through surplus. **Appendix P** of this document describes a sample procedure for controlling procurement and use of radioactive material that is acceptable to DHFS.

Licensees are required to develop, implement, and maintain written procedures for safely receiving and opening packages in accordance with *HFS 157.29(6)*. **Appendix P** of this document describes a sample procedure for safely receiving and opening packages containing licensed materials that is acceptable to DHFS.

Applicants for a broad scope license are required to establish appropriate administrative controls and provisions relating to material control and accounting that are necessary to assure safe operations. Licensees use various methods to account for receipt, use, transfer, disposal, and radioactive decay of unsealed licensed material (e.g., computer programs, manual ledgers, log books, etc.). These methods help to assure that licensee and individual authorized user possession limits are not exceeded. Licensees who possess sealed sources are required to perform periodic inventories. The frequency of these inventories is normally established by a license condition as every 6 months.

Licensed material is considered to become part of the licensee's inventory at the time that it is received by the licensee, be it during normal working hours or after hours when delivered by the carrier in accordance with procedures established by the licensee. If, through some error, the licensee receives material it is unauthorized to possess or receives quantities of material that would result in the total inventory being in excess of license possession limits, the licensee should place the package in secure storage and arrange for the return of these materials in a timely manner. If return of the materials is not possible, the licensee should contact DHFS and request issuance of an expedited license amendment. The materials must not be used until the amendment is granted.

HFS 157.28(1)(a) and 157.28(1)(b) require licensees to secure radioactive materials from unauthorized removal or access while in storage and to control and maintain constant surveillance over licensed material that is not in storage. Applicants for broad scope licenses must establish policies and procedures to ensure compliance with security requirements.

Licensees must maintain records of receipt, use, transfer, and disposal of all licensed material. **Table 2** below lists each type of record and how long the record must be maintained.

Table 2: Record Maintenance

| Type of Record | How Long Record Must be Maintained |
|------------------------------|-----------------------------------------------------------------------------------|
| Receipt | For as long as the material is possessed until 3 years after transfer or disposal |
| Transfer | For 3 years after transfer |
| Disposal | Until DHFS terminates the license |
| Important to decommissioning | Until the site is released for unrestricted use |

Information about locations where licensed material is used or stored is among the records important to decommissioning and required by *HFS 157.15*. Also refer to the section titled "Financial Assurance and Recordkeeping for Decommissioning" in this document.

Response from Applicant:

| Item 12.3 Material Receipt And Accountability (Check all boxes) | | | |
|----------------------------------------------------------------------------------------------------------------------------|--|--|--|
| A description of administrative procedures to assure control of procurement and use of radioactive material is attached. | | | |
| AND | | | |
| A description of administrative controls and provisions relating to material control, accounting and security is attached. | | | |
| AND | | | |
| ☐ We will develop, implement, and maintain procedures for safe opening of packages containing radioactive material. | | | |

Note: If you are a Type A broad scope licensee or applicant, and you want the flexibility to revise your radiation safety receipt and accountability program without amendment of the license as discussed in the section titled **'Purpose of this Guide'** and **Item 6**, Radiation Safety Committee, describe the process that will be used to revise and implement your submitted program.

12.4: Occupational Dosimetry

Rule: HFS 157.22(1); 157.22(2); 157.22(3); 157.22(4); 157.22(7); 157.22(8); 157.25(1); 157.25(2); 157.27(3); 157.31(7); and Chapter HFS 157 'Radiation Protection', Appendix E

Criteria: The use of individual monitoring devices for external dose is required, pursuant to *HFS* 157.25(2), for:

- Adults who are likely to receive an annual dose in excess of any of the following (each evaluated separately):
 - 0.005 Sv (0.5 rem) deep-dose equivalent.
 - 0.015 Sv (1.5 rems) eye dose equivalent.
 - 0.05 Sv (5 rems) shallow-dose equivalent to the skin.
 - 0.05 Sv (5 rems) shallow-dose equivalent to any extremity.
- Minors who are likely to receive an annual dose in excess of any of the following (each evaluated separately):
 - 1.0 mSv (0.1 rem) deep-dose equivalent.
 - 1.5 mSv (0.15 rem) eye dose equivalent.

- 0.005 Sv (0.5 rem) shallow-dose equivalent to the skin.
- 0.005 Sv (0.5 rem) shallow-dose equivalent to any extremity.
- Declared pregnant women who are likely to receive an annual dose from occupational exposures in excess of 1.0 mSv (0.1 rem) deep-dose equivalent, although the dose limit applies to the entire gestation period.
- Individuals entering a high or very high radiation area.

Internal exposure monitoring is required, pursuant to *HFS 157.25(2)*, for:

- Adults likely to receive in 1 year an intake in excess of 10% of the applicable Annual Limit of Intake (ALI) for ingestion and inhalation.
- Minors and declared pregnant women likely to receive in 1 year a committed effective dose equivalent in excess of 1.0 mSv (0.1 rem).

Discussion: If an adult is likely to receive in 1 year a dose greater than 10% of any applicable limit, monitoring is required. The licensee should perform an evaluation of the dose the individual is likely to receive prior to allowing the individual to receive the dose. This evaluation need not be made for every individual. Evaluations can be made for employees with similar job functions or work areas.

If this prospective evaluation shows that the individual is not likely to exceed 10% of any applicable limit, there are no recordkeeping or reporting requirements in regard to the individual's exposure. For individuals who received exposure at other facilities in the current year, the previous dose need not be considered in this prospective evaluation. Only dose that could be received at the facility performing the evaluation need be considered when determining the need for monitoring, and therefore, recordkeeping and reporting requirements. If it is determined that monitoring is not required and a subsequent evaluation shows that the 10% threshold has or will be exceeded, the dose received when monitoring was not provided should be estimated, recorded, and reported. These estimates can be based on any combination of work location radiation monitoring or survey results, monitoring results of individuals in similar work situations or other estimates to produce a "best estimate" of the actual dose received.

If monitoring is not required to demonstrate compliance with all limits but is required relative to one or more specific limits, the licensee should enter "NR" for "Not Required" in the blocks on DPH Form 45003 'Occupational Exposure Records Per Monitoring Period' to indicate the areas for which monitoring was not required (e.g., extremity or skin doses). Where monitoring was provided but not measurable, the licensee should enter "ND" for "Not Detectable."

If the prospective evaluation shows that the individual is likely to exceed 10% of an applicable limit, then monitoring, and reporting of the results of monitoring performed regardless of the actual dose received, is required. If air sampling or bioassay is required, discussion of air sampling or bioassay should provide enough detail that the DHFS staff is assured that appropriate steps will be taken to manage and monitor such exposure.

Table 3: Nuclear Regulatory Commission Documents that Contain Guidance Relating to Personnel Monitoring and Bioassay that may be Applicable

| Regulatory Guide 8.7, Revision 1 | Instructions for Recording and Reporting Occupational Radiation Exposure Data | |
|-----------------------------------|-------------------------------------------------------------------------------------------------------|--|
| Regulatory Guide 8.9, Revision 1 | Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program | |
| Regulatory Guide 8.20 | Applications of Bioassay for I-125 and I-131 | |
| Regulatory Guide 8.21 | Health Physics Surveys for Byproduct Material at NRC- Licensed Processing and Manufacturing Plants | |
| Regulatory Guide 8.23 | Radiation Safety Surveys at Medical Institutions | |
| Regulatory Guide 8.25, Revision 1 | Air Sampling in the Workplace | |
| Regulatory Guide 8.34 | Monitoring Criteria and Methods to Calculate Occupational Doses | |
| Regulatory Guide 8.35 | Planned Special Exposures | |
| Regulatory Guide 8.36 | Radiation Dose to the Embryo/Fetus | |
| Regulatory Guide 8.37 | ALARA Levels for Effluents from Materials Licensees | |
| NUREG-0938 | Information for Establishing Bioassay Measurements and Evaluation of Tritium Exposure | |
| NUREG-4884 | Interpretation of Bioassay Measurements | |
| ANSI N13.30-1996 | "Performance Criteria for Radiobioassay", dated 1996 | |

Additional References for Further Reading:

- 1. U.S. Department of Energy DOE G 441.1-2, "Occupational ALARA Program Guide," March 17, 1999.
- 2. U.S. Department of Energy DOE G 441.1-3, "Internal Dosimetry Program Guide," March 17, 1999.
- 3. U.S. Department of Energy DOE G 441.1-4, "External Dosimetry Program Guide," March 17, 1999.
- 4. U.S. Department of Energy DOE G 441.1-8, "Air Monitoring Guide," March 17, 1999.
- 5. U.S. Department of Energy DOE G 441.6-1, "Evaluation and Control of Radiation Dose to the Embryo/Fetus," April 1998.

Response from Applicant:

| Ite | Item 12.4 Occupational Dosimetry (Check one box) | | | |
|-----|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|--|--|
| | ☐ We will maintain, for inspection by DHFS, documentation demonstrating that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10 percent of the allowable limits in s. HFS 157.22. | | | |
| | OR | | | |
| | We will provide dosimetry processed and evaluated by a NVLAP-approved processor that is exchanged at a frequency recommended by the processor. | | | |

12.5: Public Dose

Rule: HFS 157.03; 157.23(1); 157.23(2); 157.28(1)(a); 157.28(1)(b); and 157.31(8)

Criteria: Licensees must ensure that licensed material will be used, transported, stored, and disposed in such a way that the total effective dose equivalent (TEDE) to members of the public will not exceed more than 1 mSv (100 mrem) in one year, and the dose in any unrestricted area will not exceed 0.02 mSv (2 mrem) in any one hour.

Discussion: Public dose is defined in *HFS 157.03* as "the dose received by a member of the public from exposure to radiation and/or radioactive material released by a licensee, or to any other source of radiation under the control of a licensee". Public dose excludes doses received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with HFS *157.62(8)*, from voluntary participation in medical research programs, and from the licensee's disposal of radioactive material into sanitary sewerage in accordance with *HFS 157.30(3)*. Whether the dose to an individual is an occupational dose or a public dose depends on the individual's assigned duties. It does not depend on whether the individual is in a restricted area, a controlled area, or an unrestricted area when the dose is received.

There are both external exposure components and internal exposure components of public dose. The licensee should review all possible internal and external exposure pathways and decide which are applicable to its operations.

Licensees should design a monitoring program to ensure compliance with *HFS 157.23(2)*. The extent and frequency of monitoring will depend upon the nature of the licensee's operations, potential releases, exposures and pathways to cause public dose or environmental contamination. For additional guidance regarding monitoring of effluents, refer to **Item 12.7 Surveys.**

HFS 157.31(8) requires that licensees maintain survey and monitoring records that demonstrate compliance with the dose limits for members of the public until DHFS terminates the license.

For guidance about accepted methodologies for determining doses to members of the public, see **Appendix Q** of this document.

Response from Applicant:

Item 12.5 Public Dose

No response is required, in this license application, however the licensee's evaluation of public dose will be examined during an inspection.

12.6: Safe Use of Radionuclides and Emergency Procedures

Rule: HFS 157.88(1); 157.21; 157.28(1)(a); 157.28(1)(b); 157.32(1)-(3); 157.13(17); 157.13(1); HFS 157 Appendices P & Q; 157.13(9)(b) & (10); 157.13(3)(c); 157.13(3)(d); and 157.13(3)(e)

Criteria: Licensees are required, pursuant to the rules stated above, to:

- Keep radiation doses to workers and members of the public ALARA
- Ensure security of licensed material
- Make required notifications to DHFS of events.

Discussion: Licensees are responsible for developing and implementing procedures to ensure the security and safe use of all licensed material from the time it arrives at their facility until it is used, transferred, and/or disposed. The written procedures should provide reasonable assurance that only appropriately trained personnel will handle and use licensed material without undue hazard to themselves, other workers, or members of the public.

All licensed materials that are stored in controlled or unrestricted areas must be secured from unauthorized access or removal, so that individuals who may not be knowledgeable about radioactive materials cannot be exposed to or contaminated by the material, and individuals cannot take the material. When any licensed materials are in use in controlled or unrestricted areas, they must be under constant surveillance so that the radiation worker can prevent others from becoming contaminated by or exposed to the material, or prevent persons from removing the material from the area.

Acceptable methods for securing material will vary from one facility to another. Some alternatives used by licensees include:

- Storage and use of licensed materials only in restricted areas;
- Limiting access to an entire facility or building or portion of the building only to radiation workers;
- Providing storage areas that can be locked to prevent access to the material; and
- Implementing procedures that require a radiation worker to be within "line of sight" of the materials whenever licensed materials are in use.

The applicant should develop procedures that clearly state acceptable methods to secure licensed material at your facility. Particular attention may be required at facilities that may have unusual needs due to the activities performed, such as hot cells, animal care facilities, and waste processing facilities. Applicant's security procedures may be in a separate document or included in the "General Safety Procedures."

Applicants should develop radioisotope-specific procedures based on the respective hazards associated with the radioisotopes. General safety guidelines are described in **Appendix R** of this document. Licensees are encouraged to use these guidelines in developing procedures for the safe use of radioisotopes.

Licensees need to identify all areas that require posting in accordance with *HFS 157.29(2)*, unless they meet the exemptions listed in *HFS 157.29(3)*. In addition, containers of licensed material (including radioactive waste) must be labeled in accordance with *HFS 157.29(4)*, unless they meet the exemptions in *HFS 157.29(5)*.

Applicants need to establish written procedures to handle emergencies ranging from a minor spill to a major accident that may require intervention by outside emergency response personnel. These procedures should include provisions for immediate response, after-hours notification, handling of each type of emergency, equipment, and the appropriate roles of users and the radiation safety staff. Except for minor spills or releases of radioactivity that can be controlled and cleaned up by the user, individual users should have a clear understanding of their limitations in an emergency, with step-by-step instructions and clear direction of whom to contact. Emergency Procedures that are acceptable to DHFS are described in **Appendix R** of this document.

Emergency spill kits should be strategically placed in well-marked locations for use by all users and the radiation safety staff. All equipment should be periodically inspected for proper operation and replenished, as necessary. The licensee should also consider establishing an Emergency Response Team composed of individuals experienced in various emergency response functions (e.g., radiological, medical, emergency management, security, and fire protection).

HFS 157.32 and 157.13(17) require certain incidents and emergencies be reported to DHFS. Appendix N of this document provides examples of some events that require notification and/or reports. Note that Appendix N is not all inclusive, as there are other notification and/or reporting requirements that may apply to your specific program (i.e. Chapter HFS 157 'Radiation Protection', subchapters IV, V, VI, VII, etc.).

If you plan to possess quantities of material in excess of the applicable amounts listed in **Chapter HFS**157 'Radiation Protection', Appendix P, then you may also be required to submit an "Emergency Response Plan for Responding to a Release." See Item 9, Unsealed and/or Sealed Radioactive Material for specific information related to this requirement.

Response from Applicant:

| Iter | Item 12.6 Safe Use Of Radionuclides And Emergency Procedures (Check one box) | | | |
|------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|--|--|
| - | We will develop, implement and maintain procedures for the safe use of radionuclides and emergencies that will meet the criteria in the section titled 'Safe Use of Radionuclides and Emergency Procedures' in WISREG "Guidance for Licenses of Broa Scope." (Procedures are attached) | | | |
| | OR | | | |
| | We will follow procedures for the safe use of radionuclides and emergencies in Appendix R of WISREG "Guidance for Licenses of Broad Scope." | | | |

Note: If you are a Type A broad scope licensee or applicant, and you want the flexibility to revise your radiation safety safe use and emergency procedures without amendment of the license as discussed in the section titled **'Purpose of this Guide'** and **Item 6**, Radiation Safety Committee, describe the process that will be used to revise and implement your submitted procedures.

Item 12.7: Leak Test

Rule: HFS 157.25(1); 157.06(3); 157.13(3)(c); 157.13(3)(d); 157.13(3)(e); 157.39; 157.45(4); 157.62(5); 157.73(22); 157.52(5); 157.52(6); and 157.52(7)

Criteria: DHFS requires testing to determine whether there is any radioactive leakage from sealed sources. Records of leak test results must be maintained.

Discussion: A leak test will be required for sealed/plated foil sources at six month intervals, as approved by DHFS in a license condition, or the NRC or an Agreement State as specified by the Sealed Source and Device (SSD) Registration Certificate. The measurement of the leak-test sample is a quantitative analysis requiring that instrumentation used to analyze the sample be capable of detecting 185 becquerels (Bq) (0.005 microcuries) of radioactivity.

Leak tests are not required if:

- Sources contain only hydrogen-3 (tritium)
- Sources contain only radioactive material with a half-life of less than 30 days
- Sources contain only a radioactive gas
- Sources contain 3.7 megabecquerels (MBq) (100 microcuries) or less of beta-emitting or gamma-emitting material or 370 kilobecquerels (kBq) (10 microcuries) or less of alpha-emitting material

• Sources are stored and are not being used (must be leak tested before use or transfer).

For more information regarding leak tests, see **Appendix T** of this document.

Response from Applicant:

| Iten | Item 12.7 Leak Tests (Check one box) | | | |
|------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------|--|--|
| | Leak tests will be performed by an organization authorized by DHFS, the NRC or an Agreement State to provide leak testing services to other licensees; or by using a leak test kit supplied by an organization licensed by DHFS, the NRC or an Agreement State to provide leak test kits to other licensees according to kit supplier's instructions. List Name and License number of organization authorized to perform or analyze leak test (Specify whether DHFS, NRC, or other Agreement State) | | | |
| | | | | |
| | Organization Name License Number | | | |
| | Note : An alternate organization may be used to perform or analyze leak test, without amending the license, provide organization is specifically authorized by DHFS, NRC, or an Agreement State. | d the | | |
| | OR | | | |
| - | We will perform leak testing and sample analysis and will follow the model procedures in Appendix T of WISREG "Guidance for Licenses of Broad Scope." (Procedures are attached) | | | |
| | OR | | | |
| | We will submit alternative procedures. (Procedures are attached) | | | |

References: See Section 8.10.8 and Appendix O of NRC NUREG 1556 Vol. 18 "Program Specific Guidance about Service Provider Licenses," and is available electronically at NRC's web site, http://www.nrc.gov, under "Electronic Reading Room," then "All Collections," the "NUREG-Series Publications."

Item 12.8: Surveys

Rule: HFS 157.25(1); 157.31(3); 157.06(3); 157.13(3)(c); 157.13(3)(d); 157.13(3)(e); 157.62(1); and 157.73(22)

Criteria: Licensees are required, pursuant to the requirements listed above, to make surveys of potential radiological hazards in their workplace. Records of surveys must be maintained.

Discussion: A survey is defined in *HFS 157.03* as, "an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of sources of radiation. When appropriate, an evaluation includes tests, physical examinations and measurements of

levels of radiation or concentrations of radioactive material present." These evaluations may be measurements (e.g., radiation levels measured with a survey instrument or results of wipe tests for contamination), calculation, or a combination of measurements and calculations. The licensees must interpret and evaluate such measurements and calculations to take appropriate action. The selection and proper use of appropriate instruments is one of the most important factors in ensuring that surveys accurately assess the radiological conditions. Surveys are also used to plan work in areas where radioactive material is present and to evaluate doses to workers and individual members of the public. In certain cases, environmental monitoring may be required to demonstrate compliance with **Chapter HFS** 157 'Radiation Protection', Subchapter III, 'Standards for Protection from Radiation'.

Surveys are required when it is necessary for the licensee to comply with **Chapter HFS 157 'Radiation Protection'** or to evaluate a radiological hazard. Surveys that may need to be performed include:

- Surveys for radioactive contamination that could be present on surfaces of floors, walls, laboratory furniture, and equipment.
- Measurements of radioactive material concentrations in air for areas where radioactive materials are handled or processed in unsealed form.
- Measurements of radioactive material concentrations in water that is released to the environment or to the sanitary sewer.
- Bioassays to determine the kinds, quantities, concentration, and location of radioactive material in the human body. A bioassay can be made by direct measurement, <u>in vivo</u> counting, or by analysis and evaluation of material excreted or removed from the human body.
- Surveys of external radiation exposure levels in both restricted and unrestricted areas.

The frequency of routine surveys depends on the nature, quantity, and use of radioactive materials, as well as the specific protective facilities, equipment, and procedures that are designed to protect the worker from external and internal exposure. Also, the frequency of the survey depends on the type of survey, such as those listed above.

Chapter HFS 157 'Radiation Protection', subchapter III, 'Standards for Protection from Radiation', does not specify limits for surface contamination. Each applicant should propose and justify

what removable surface contamination limits will be allowable before decontamination will be performed in each work area.

Appendix S of this document describes survey procedures that are acceptable to DHFS.

NRC NUREG/BR-0241, "NMSS Handbook for Decommissioning Fuel Cycle and Materials Licenses," dated March 1997, contains the current regulatory guidance concerning decommissioning of facilities and termination of licenses. Appendix B of the handbook contains a comprehensive list of NRC's decommissioning regulations and guidance. In addition, NUREG-1575, "Multi-Agency Radiation Survey and Site Investigation Manual (MARSSIM)," dated December 1997, should be reviewed by licensees who have large facilities to decommission.

Response from Applicant:

Item 12.8 Surveys (Check one box)

☐ We will develop, implement and maintain procedures for area surveys that will meet the criteria in the section titled 'Surveys' in WISREG "Guidance for Licenses of Broad Scope." (Procedures are attached)

☐ OR

☐ We will follow the procedures for area surveys in Appendix S of WISREG "Guidance for Licenses of Broad Scope."

Note: If you are a Type A broad scope licensee or applicant, and you want the flexibility to revise your radiation safety survey program without amendment of the license as discussed in the section titled **'Purpose of this Guide'** and **Item 6**, Radiation Safety Committee, describe the process that will be used to revise and implement your submitted program.

Item 12.9: Termination of Activities

Rule: HFS 157.13(9)(b); 157.13(10); 157.15; 157.13(11); 157.06(1); 157.13(18); 157.33(1); 157.33(2); 157.33(3); 157.33(4); and 157.13(2)(b)

Criteria: Pursuant to the requirements described above, the licensee must do the following:

• Notify DHFS, in writing, within 30 days of:

- Decision to permanently discontinue all activities involving materials authorized under the license.
- Notify DHFS, in writing, within 60 days of:
 - the expiration of its license
 - a decision to permanently cease licensed activities at the entire site (regardless of contamination levels)
 - a decision to permanently cease licensed activities in any separate building or outdoor area, if they contain residual radioactivity making them unsuitable for release according to NRC requirements
 - no principal activities having been conducted at the entire site under the license for a period of 24 months
 - no principal activities having not been conducted for a period of 24 months in any separate building or outdoor area, if they contain residual radioactivity making them unsuitable for release according to DHFS requirements.
- Submit decommissioning plan, if required by *HFS 157.13(11)*.
- Conduct decommissioning, as required by *HFS 157.13(11)*.
- Submit, to DHFS, a completed DPH Form 45007, "Certificate of Disposition of Materials" (Appendix B) and a demonstration that the premises are suitable for release for unrestricted use (e.g., results of final survey).
- Before a license is terminated, send all records pertaining to decommissioning to DHFS. If licensed activities are transferred or assigned in accordance with HFS 157.13(9)(b) and HFS 157.13(10), transfer records important to decommissioning to the new licensee.

Discussion: A licensee shall notify DHFS if residual radioactivity is present and if levels make the building or outdoor area unsuitable for release according to DHFS requirements. A licensee's determination that a facility is not contaminated is subject to verification by DHFS inspection.

The permanent cessation of principal activities in an individual room or laboratory may require the licensee to notify DHFS if no other licensed activities are being performed in the building. This also applies to buildings that were approved by the broad scope licensee as locations of use but not specifically named on the broad scope license.

NRC Draft Regulatory Guide DG-4006, "Demonstrating Radiological Criteria For License Termination," issued July 8, 1998 and NUREG/BR-0241, "NMSS Handbook for Decommissioning Fuel Cycle and Materials Licenses," dated March 1997, contains the current regulatory guidance concerning decommissioning of facilities and termination of licenses. Appendix B of the Handbook contains a comprehensive list of NRC's decommissioning regulations and guidance. NUREG-1575, "Multi-Agency Radiation Survey and Site Investigation Manual (MARSSIM)," dated December 1997, should be reviewed by licensees who have large facilities to decommission. An acceptable screening computer code for calculating screening values to demonstrate compliance with the unrestricted dose limits is D and D, Version 1; this was issued on August 20, 1998. Supplemental information on the implementation of the final rule on radiological criteria for license termination was published in the Federal Register (Volume 63, Number 222, Page 64132-64134) on November 18, 1998. This includes the following acceptable license termination screening values of common radionuclides for building surface contamination.

Table 4: Acceptable License Termination Screening Values of Common Radionuclides for Building Surface Contamination

| Radionuclide | Symbol | Acceptable Screening Levels* |
|----------------------|-------------------|------------------------------|
| hydrogen-3 (tritium) | ³ H | 1.2 x 10 ⁸ |
| carbon-14 | ¹⁴ C | 3.7×10^6 |
| sodium-22 | ²² Na | 9.5×10^3 |
| sulfur –35 | ³⁵ S | 1.3×10^7 |
| chlorine-36 | ³⁶ Cl | 5.0 x 10 ⁵ |
| Manganese-54 | ⁵⁴ Mn | 3.2×10^4 |
| iron-55 | ⁵⁵ Fe | 4.5×10^6 |
| cobalt-60 | ⁶⁰ Co | 7.1×10^3 |
| nickel-63 | ⁶³ Ni | 1.8×10^6 |
| Strontium-90 | ⁹⁰ Sr | 8.7×10^6 |
| Technetium-99 | ⁹⁹ Tc | 1.3×10^6 |
| iodine-129 | ¹²⁹ I | 3.5×10^4 |
| cesium-137 | ¹³⁷ Cs | 2.8 x 10 ⁴ |
| iridium-192 | ¹⁹² Ir | 7.4×10^4 |

^{*} Screening levels are based on the assumption that the fraction of removable surface contamination is equal to 0.1. For cases when the fraction of removable contamination is undetermined or higher than 0.1, users may assume, for screening purposes, that 100% of surface contamination is removable; and therefore the screening levels should be decreased by a factor of 10. Alternatively, users having site-specific data on the fraction of removable contamination (e.g., within 10% to 100% range) may calculate site-specific screening levels using D and D Version 1, based on site-specific resuspension factor. For Unrestricted Release (dpm/100 cm²) Units are disintegrations per minute per 100 square centimeters (dpm/100 cm²). 1 dpm is equivalent to 0.0167 becquerel (Bq). The screening values represent surface concentrations of individual radionuclides that may be deemed in compliance with the 0.25 mSv/yr (25 mrem/yr) unrestricted release dose limit in *HFS* 157.33(2). For radionuclides in a mixture, the "sum of fractions" rule applies; see *HFS* 157 Appendix E, Note 4. Refer to NRC Draft Guidance DG-4006 for further information on application of the values in this table.

Response from Applicant:

Item 12.9 Termination Of Activities

No response is required from the applicant during the application process. Refer to section titled "Termination of Activities" in WISREG "Guidance for Licenses of Broad Scope" for further information.

Item 12.10: Transportation

Rule: HFS 157.21; 157.13(15); 157.06(1); 157.13(18); 157.13(3)(c); 157.13(3)(d); 157.13(3)(e); 157.43; 157.92(3); 157.93(4); 157.93(5); 157.93(6); 157.94(1); and 49 CFR Parts 171-178

Criteria: Broad Scope licensees who will transport or ship licensed material, including radioactive waste, must develop, implement, and maintain safety programs for transport of radioactive material to ensure compliance with DHFS, and U.S. Department of Transportation (DOT) regulations.

Discussion: Department of Transportation regulations (**49 CFR**) were written to help assure that transportation of hazardous materials in commerce is transported uniformly and safely. Wisconsin licensees who transport radioactive material (hazardous material) in commerce would, therefore, be required to comply with all applicable regulations found in DOT. However, many Wisconsin licensees routinely transport radioactive material that is not in commerce. **Appendix U** of this document provides an overview of the transportation requirements commonly affecting Wisconsin licensees. Licensees may also wish to review NUREG-1660, "U.S.-Specific Schedules of Requirements for Transport of Specified Types of Radioactive Material Consignments," published jointly by NRC and DOT in November 1998.

Knowing how *HFS 157.92(3)* and *49 CFR* interrelate is very important to broad scope programs. Therefore, it is imperative that your radiation safety staff is thoroughly familiar with *HFS 157.92(3)* and *49 CFR* in order to comply and to take full advantage of the flexibility inherent in DOT requirements.

Licensed material, including radioactive waste, must be packaged and transported in accordance with DHFS and DOT requirements if the transportation involves the use of public highways. In addition, broad scope licensees need to develop and maintain their own radiation safety procedures for transporting licensed material within their own facilities if such transportation does not involve the use of public highways.

Licensees also need to consider the safety of all individuals who may handle or may come in contact with the packages containing licensed material. Thus, the primary considerations in packaging licensed material should be to ensure that package integrity is not compromised during transport and that the radiation levels (including removable contamination levels) at the package surfaces not only meet the regulatory requirements of *HFS 157.92(3)*, but are ALARA.

Licensees shipping radioactive waste for disposal must prepare appropriate documentation as specified in Chapter HFS 157 'Radiation Protection', Appendix G.

Response from Applicant:

Item 12.10 Transportation

No response is needed from applicant during the licensing process; this issue will be reviewed during inspection.

Reference: 'A Review of Department of Transportation Regulations for Transportation of Radioactive Materials (1998 revision)' can be obtained by calling DOT's Office of Hazardous Material Initiatives and Training at (202) 366-4900 or by accessing their website at http://hazmat.dot.gov/pubtrain/ramreview.pdf.

Item 13: Waste Management

Rule: HFS 157.25(1); 157.30(1); 157.30(2); 157.30(3); 157.30(4); 157.30(5); 157.30(6); 157.30(7); 157.31(9); 157.06(1); and 157.13(18)

Criteria: Radioactive waste must be disposed of in accordance with regulatory requirements, and appropriate records of waste disposal must be maintained.

Discussion: The applicant should discuss the methods for management and disposal of radioactive waste. The program should include procedures for handling of waste, safe and secure storage, waste characterization, waste minimization, and disposal of radioactive waste. Appropriate training should be provided to waste handlers. Licensees may not receive radioactive waste from other licensees for processing, storage, or disposal unless specifically authorized.

The U.S. Environmental Protection Agency (EPA) issued guidance for developing a comprehensive program to reduce hazardous waste. This guidance was transmitted to NRC licensees by the NRC in IN-94-23, "Guidance to Hazardous, Radioactive, and Mixed Waste Minimization Program," dated March 1994. The application should include, where appropriate for the types of waste involved, provisions for monitoring and segregating waste materials (radioactive from nonradioactive, short from long half-life, liquid from solid waste, etc.).

The following methods of waste disposal may be considered and should be addressed in the application as appropriate.

Transfer to an Authorized Recipient

Waste may be transferred to a recipient (usually a waste disposal service company or the original supplier) who is properly licensed to receive such waste in accordance with *HFS 157.30(1)*. Each shipment must comply with all applicable DHFS and DOT requirements.

Licensees should implement procedures to reduce the volume of radioactive waste for final disposal in an authorized low-level radioactive waste (LLW) disposal facility. These procedures include volume reduction by segregating, consolidating, compacting, or allowing certain waste to decay in storage. Waste compaction or other treatments can reduce the volume of radioactive waste, but such processes may pose additional radiological hazards (e.g., airborne radioactivity) to workers, members of the public, and the environment. Safety procedures to address these concerns should be implemented.

Decay-In-Storage (DIS) and Extended Interim Storage

DHFS has concluded that materials with half-lives of less then or equal to 120 days are appropriate for DIS and interim storage. The minimum holding period for decay is ten half-lives of the longest lived radioisotope in the waste. Such waste may be disposed of as ordinary trash if radiation surveys (performed in a low background area and without any interposed shielding) of the waste at the end of the holding period indicate that radiation levels are indistinguishable from background. All radiation labels must be defaced or removed from containers and packages prior to disposal as ordinary trash. If the decayed waste is compacted, all labels that are visible in the compacted mass must also be defaced or removed.

DHFS does not consider storage as a substitute for final disposal of radioactive wastes. Other than storage for radioactive decay, LLW should be stored only when disposal capacity is unavailable, and for no longer than is necessary. NRC Information Notice No. 90-09, "Extended Interim Storage of Low-Level Radioactive Waste for Fuel Cycle and Material Licensees," dated February 1990, provides guidance to licensees for requesting an amendment to authorize extended interim storage of LLW.

A sample procedure for DIS is contained in **Appendix V** of this guidance document.

Release into Air and Water

Release of radioactive material into air and water must conform to the requirements described in *HFS* 157.23(2). The applicant should discuss the monitoring and control mechanisms in place to ensure compliance with the requirements. Applicants are reminded of the "constraint" on air emissions of radioactive material required by *HFS* 157.21(4), which effectively reduces the limits specified in **Chapter HFS** 157 'Radiation Protection', Appendix E, Table II, for release of gaseous effluents. Applicants, who are considering release of radioactive material into air and water should review NRC Regulatory Guide 8.37, "ALARA Levels for Effluents From Materials Facilities," dated July 1993. Regulatory Guide 8.37 deals with the application of ALARA in controlling gaseous and liquid effluents, and references documents containing acceptable methods of effluent monitoring.

Licensees considering disposal by release to the sanitary sewerage system must comply with the requirements of *HFS 157.30(3)*. *HFS 157.30(3)* authorizes disposal of licensed material by release into a public sanitary sewerage system if certain conditions are met. Licensees are responsible for demonstrating that licensed materials discharged into the public sewerage system are readily soluble in water or are biological materials that are readily dispersible in water. NRC Information Notice, No. 94-07, "Solubility Criteria for Liquid Effluent Releases to Sanitary Sewerage Under the Revised 10 CFR 20," dated January 1994, provides the criteria for evaluating solubility of waste. Licensees should carefully consider the possibility of reconcentration of radioisotopes that are released into the sewer. The NRC alerted licensees to the potentially significant problem of reconcentration of radionuclides released to sanitary sewerage systems in Information Notice No. 84-94, "Reconcentration of Radionuclides Involving Discharges into Sanitary Sewerage Systems Permitted Under 10 CFR 20.203 (now 10 CFR 20.2003)," dated December 1984.

Applicants should provide procedures that will ensure that all releases of radioactive waste into the sanitary sewerage meet the criteria stated in *HFS 157.30(3)* and do not exceed the monthly and annual limits specified in rule. Licensees are required to maintain accurate records of all releases of licensed material into the sanitary sewerage. A sample procedure for disposal of radioactive waste via sanitary sewer and maintenance of records is described in **Appendix V** of this guidance document.

If your facility maintains a private sewerage treatment system, a septic system, or leach fields, the requirements of *HFS 157.30(3)* are not applicable for releases to these systems (see *HFS 157.03*, definition of "sanitary sewerage"). You may make releases of liquids to private sewerage systems, septic systems, or leach fields as effluents released to unrestricted areas pursuant to *HFS 157.23(2)(b) 2.a.*

If liquid releases are made to a private sewerage treatment system, septic system, or leach field, the sludges or other solids from these systems may become contaminated with radioactive material. Applicants should describe the monitoring planned for these systems. Contaminated sludges will be required to be disposed of as radioactive waste using one of the methods described in this section. Applicants may obtain approval of alternative disposal methods through application to DHFS, as described in *HFS* 157.30(2).

Incineration

Applicants who wish to treat or dispose of licensed material by incineration must comply with the requirements of *HFS 157.30(4)*. Applicants proposing incineration should be aware that notification and approval by the Wisconsin Department of Natural Resources is required before ash may be disposed of as ordinary waste in Wisconsin. However, approval of incineration pursuant to *HFS 157.30(4)* does not require notification and approval by the Wisconsin Department of Natural Resources if the ash is disposed as radioactive waste or transferred to a specific licensee. Nuclear Regulatory Commission (NRC) Policy and Guidance Directive PG 8-10, "Disposal of Incinerator Ash as Ordinary Waste," dated January 1997, provides guidance relative to the disposal of ash. A sample procedure for incineration of waste is described in **Appendix V** of this guidance document.

Applicants who are considering disposal of radioactive material by incineration should review NRC Regulatory Guide 8.37, "ALARA Levels for Effluents From Materials Facilities," dated July 1993. Regulatory Guide 8.37 deals with the application of ALARA in controlling gaseous and liquid effluents and references documents containing acceptable methods of effluent monitoring.

Waste Volume Reduction

Waste volume reduction operations that could create a radiological hazard to licensee employees or the general public must be described in detail in the application. A sample procedure for waste compaction is described in **Appendix V** of this guidance document.

Disposal of Specific Waste As If It Were Not Radioactive

The following radioactive wastes may be disposed of as non-radioactive waste:

- Liquid scintillation medium containing no more than 1.85 kBq (0.05 microcuries) of hydrogen-3, iodine-125 or carbon-14 per gram of the medium; and
- Animal carcasses or animal tissue containing no more than 1.85 kBq (0.05 microcuries) of hydrogen-3, iodine-125 or carbon-14 per gram averaged over the weight of the entire animal.

Applicants should have procedures that will ensure that the above limits are not exceeded and that the disposal of animal tissue or carcasses containing licensed material is in a manner that will not permit their use either as food for humans or animals. Licensees must maintain accurate records of these disposals.

Burial

Licensees who were previously authorized by the Nuclear Regulatory Commission to bury radioactive materials pursuant to *10 CFR 20.304* prior to January 28, 1981, should describe the locations, condition and current status of these former sites, i.e., controlled or uncontrolled, active monitoring of the site, and current condition of burial site.

Other Methods Specifically Approved by DHFS Pursuant to HFS 157. 30(2)

Applicants may also request alternate methods for the disposal of radioactive waste generated at their facilities. Such requests must describe the waste containing licensed material, including the physical and chemical properties that may be important to assess risks associated with the waste, and the proposed manner and conditions of waste disposal. Additionally, the applicant must submit its analysis and evaluation of pertinent information on the nature of the environment, nature and location of other affected facilities and procedures to ensure that radiation doses are maintained ALARA and within regulatory limits.

The application should describe the ALARA considerations taken before disposal of radioactive materials. Discuss the potential for unmonitored or unanticipated release of radioactive materials to work areas and from release points, i.e., hoods and incinerator stacks. To be in compliance with the ALARA philosophy stated in *HFS 157.21(2)*, radioactive material waste stream concentrations should be a fraction (generally 10% to 20%) of the limits specified in **Chapter HFS 157 'Radiation Protection'**, **Appendix E, Table II.** Furthermore, due to the variability of inventory control programs for monitoring disposal and releases of radioactive material in use, a program for physically measuring releases should be in place whenever releases exceed the specified ALARA action point.

Applicants should contact DHFS for guidance on how to obtain approval for alternate methods.

Sealed Sources

Because of the difficulties and costs associated with disposal of sealed sources, applicants should preplan the disposal. Applicants may want to consider contractual arrangements with the source supplier as part of a purchase agreement.

Response from Applicant:

Item 13 Waste Management (Check box) ☐ We will develop, implement and maintain procedures for waste collection, storage, and the disposal of radioactive material, that will meet the criteria in the section titled 'Waste Management' in WISREG "Guidance for Licenses of Broad Scope." (Procedures are attached) Note: Appendix V in WISREG "Guidance for Licenses of Broad Scope" provides sample procedures for waste management.

Note: Applicants do not need to provide information to DHFS if they plan to dispose of Low Level Waste via transfer to an authorized recipient or to dispose of liquid scintillation media or animals containing low levels of hydrogen-3, iodine-125 or carbon-14, as authorized by *HFS 157.30(5)*.

Item 14: Fees

The next two items on DPH form 45015 are to be completed on the form itself.

On DPH form 45015, enter the appropriate fee category from *HFS 157.10* and the amount of the fee enclosed with the application.

Response from Applicant:

| Item 14 License Fees (Refer to Wisconsin Administrative Code HFS 157.10) | | | | | | |
|--------------------------------------------------------------------------|-----------------------|------|-----------------|--|--|--|
| Category: | License fee enclosed: | | | | | |
| | ☐ Yes | □ No | Amount Enclosed | | | |

Item 15: Certification

Representatives of the corporation or legal entity filing the application should date and sign DPH Form 45015. Representatives signing an application must be authorized to make binding commitments and to sign official documents on behalf of the applicant. As discussed previously in **"Management Responsibility,"** signing the application acknowledges management's commitment and responsibilities for the radiation protection program. DHFS will return all unsigned applications for proper signature.

Note:

- It is a criminal offense to make a willful false statement or representation on applications or correspondence ($HFS\ 157.05(2)(b)$).
- When the application references commitments, those items become part of the licensing conditions and regulatory requirements.

Response from Applicant:

| Item 15 | | | | | | |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|--|--|--|--|--|
| I hereby certify that this application was prepared in conformance with Wisconsin Administrative Code Chapter HFS 157 "Radiation Protection" and that all information contained herein, including any supplements attached hereto, is true and correct to the best of my knowledge and belief. | | | | | | |
| SIGNATURE - Applicant Or Authorized Individual | Date signed | | | | | |
| | | | | | | |
| Print Name and Title of above signatory | | | | | | |

APPENDIX A: DPH 45015

"APPLICATION FOR RADIOACTIVE MATERIAL LICENSE FOR BROAD SCOPE"



http://dhfs.wisconsin.gov/forms/DPH/dph45015.pdf

APPENDIX B:

DPH 45007

"CERTIFICATE OF DISPOSITION OF MATERIALS"



http://dhfs.wisconsin.gov/forms/DPH/dph45007.pdf

APPENDIX C:

RESERVED

APPENDIX D : RESERVED

APPENDIX E : RESERVED

APPENDIX F: RESERVED

APPENDIX G:

RESERVED

APPENDIX H:

INFORMATION NEEDED FOR TRANSFER OF CONTROL APPLICATION

Information Needed for Transfer of Control Application

Licensees must provide full information and obtain DHFS's prior written consent before transferring control of the license; some licensees refer to this as "transferring the license." Provide the following information concerning changes of control by the applicant (transferor and/or transferee, as appropriate). If any items are not applicable, so state.

- 1. The new name of the licensed organization. If there is no change, the licensee should so state.
- 2. The new licensee contact and telephone number(s) to facilitate communications.
- 3. Any changes in personnel having control over licensed activities (e.g., officers of a corporation) and any changes in personnel named in the license such as radiation safety officer, authorized users, or any other persons identified in previous license applications as responsible for radiation safety or use of licensed material. The licensee should include information concerning the qualifications, training, and responsibilities of new individuals.
- 4. An indication of whether the transferor will remain in non-licensed business without the license.
- 5. A complete, clear description of the transaction, including any transfer of stocks or assets, mergers, etc., so that legal counsel is able, when necessary, to differentiate between name changes and transferring control.
- 6. A complete description of any planned changes in organization, location, facility, equipment, or procedures (i.e., changes in operating or emergency procedures).
- 7. A detailed description of any changes in the use, possession, location, or storage of the licensed materials.
- 8. Any changes in organization, location, facilities, equipment, procedures, or personnel that would require a license amendment even without transferring control.

- 9. An indication of whether all surveillance items and records (e.g., calibrations, leak tests, surveys, inventories, and accountability requirements) will be current at the time of transfer. Provide a description of the status of all surveillance requirements and records.
- 10. Confirmation that all records concerning the safe and effective decommissioning of the facility, pursuant to *HFS 157.15*; public dose; and waste disposal by release to sewers, incineration, radioactive material spills, and on-site burials, have been transferred to the new licensee, if licensed activities will continue at the same location, or to DHFS for license terminations.
- 11. A description of the status of the facility. Specifically, the presence or absence of contamination should be documented. If contamination is present, will decontamination occur before transfer? If not, does the successor company agree to assume full liability for the decontamination of the facility or site?
- 12. A description of any decontamination plans, including financial assurance arrangements of the transferee, as specified in *HFS 157.15*. Include information about how the transferee and transferor propose to divide the transferor's assets and responsibility for any cleanup needed at the time of transfer.
- 13. Confirmation that the transferee agrees to abide by all commitments and representations previously made to DHFS by the transferor. These include, but are not limited to: maintaining decommissioning records required by *HFS 157.15*; implementing decontamination activities and decommissioning of the site; and completing corrective actions for open inspection items and enforcement actions.

With regard to contamination of facilities and equipment, the transferee should confirm, in writing, that it accepts full liability for the site, and should provide evidence of adequate resources to fund decommissioning; or the transferor should provide a commitment to decontaminate the facility before transferring control.

With regard to open inspection items, etc., the transferee should confirm, in writing, that it accepts full responsibility for open inspection items and/or any resulting enforcement actions; or the transferee proposes alternative measures for meeting the requirements; or the transferor provides a commitment to close out all such actions with DHFS before license transfer.

- 14. Documentation that the transferor and transferee agree to transferring control of the licensed material and activity, and the conditions of transfer; and the transferee is made aware of all open inspection items and its responsibility for possible resulting enforcement actions.
- 15. A commitment by the transferee to abide by all constraints, conditions, requirements, representations, and commitments identified in the existing license. If not, the transferee must provide a description of its program to ensure compliance with the license and rules.

References: The information above is contained in NRC IN 89-25, Revision 1, "Unauthorized Transfer of Ownership or Control of Licensed Activities." See the Notice of Availability (on the inside front cover of this report) to obtain copies.

APPENDIX I: INFORMATION NEEDED FOR FIELD USE OF

RADIOACTIVE MATERIAL

If you desire to perform field studies in which licensed material is deliberately released to the environment for the purposes of studies, please provide the following information:

- 1. A complete application describing the type and amount of material to be used, the location of use, and training and experience of the individual using the material.
- 2. A complete experimental protocol.
- A description of the amount of radioactive material to be released in the field, decontamination
 procedures at the conclusion of the experiment, if appropriate, and procedures for minimizing
 releases.
- 4. A description of the expected radiation dose to humans.
- 5. A description of the proposed methods of disposal of radioactive waste generated during the field use of radioactive material.
- 6. Written permission from the property owner to use radioactive materials at the proposed site.

APPENDIX J: Sample Delegation of Authority for Radiation Safety Officer

| Memorandum To: All Employees | | | | | |
|-------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------|--|--|--|--|
| From: | Chief Executive Officer | | | | |
| Subject: | Delegation of Authority for Radiation Safety Officer | | | | |
| | | | | | |
| | | | | | |
| | has been appointed Radiation Safety Officer and is responsible for | | | | |
| ensuring the safe use of radioactive material. The Radiation Safety Officer is responsible for managing the | | | | | |
| radiation safety program; identifying radiation safety problems; initiating, recommending, or providing | | | | | |
| corrective actions; verifying implementation of corrective actions; and ensuring compliance with rules for | | | | | |
| the use of radioactive material. The Radiation Safety Officer is hereby delegated the authority necessary | | | | | |
| to meet these respon | nsibilities. | | | | |

The Radiation Safety Officer has the authority to immediately stop any operations involving the use of radioactive material in which health and safety may be compromised or may result in non-compliance with DHFS requirements.

APPENDIX K:

RADIONUCLIDES CLASSIFIED ACCORDING TO RELATIVE TOXICITY

(Excerpted from IAEA Safety Standard, Safety Series No. 1,

"Safe Handling of Radionuclides, 1973 Edition")

This table is not all-inclusive and is meant to be used as an example only. Based on chemical/physical form, need and quantities, your classification scheme may differ from that of the IAEA excerpt.

Table 5: Radionuclides Classified According to Relative Radiotoxicity (Excerpted from IAEA Safety Standard, Safety Series No. 1, "Safe Handling of Radionuclides, 1973 Edition")

| Group 1: Very High Radiotoxicity | | | | | | | | | |
|----------------------------------|-------------------|-------------------|-------------------|-------------------|--------------------|--------------------|-------------------|--------------------|-------------------|
| ²¹⁰ Pb | ²²⁶ Ra | ²²⁷ Th | ²³¹ Pa | ²³³ U | 238 | Pu | ²⁴³ Am | ²⁴⁴ Cm | ²⁴⁹ Cf |
| ²¹⁰ Po | ²²⁸ Ra | •••• | •••• | •••• | | | •••• | •••• | •••• |
| Group 2: High Radiotoxicity | | | | | | | | | |
| ²² Na | ⁵⁶ Co | ⁹⁵ Zr | ¹²⁵ Sb | ^{131}I | 144 | Се | ¹⁸¹ Hf | ²⁰⁷ Bi | ²²⁸ Ac |
| ³⁶ Cl | ⁶⁰ Co | ^{125}I | ¹⁹² Ir | •••• | | | •••• | •••• | |
| Group 3: Moderate Radiotoxicity | | | | | | | | | |
| ⁷ Be | ⁴⁸ Sc | ⁶⁵ Zn | ⁹¹ Sr | ¹⁰³ Ru | ^{125m} Te | ¹⁴⁰ La | ¹⁵³ Gd | $^{187}\mathbf{W}$ | ¹⁹⁸ Au |
| ¹⁴ C | ⁴⁸ V | ^{69m} Zn | ⁹⁰ Y | ³² P | ³⁵ S | ⁵¹ Cr | ²⁴ Na | | |
| Group 4: Low Radiotoxicity | | | | | | | | | |
| ^{3}H | ^{58m} Co | ⁷¹ Ge | ⁸⁷ Rb | ⁹⁷ Nb | 103m Rh | ^{131m} Xe | ¹²⁵ Cs | ^{191m} Os | ²³² Th |
| ¹⁵ O | ⁸⁵ Kr | ^{99m} Tc | | | | | | | |

Table 6: Limitations on Activities in Various Types of Working Place or Laboratory

| Radiotoxicity of Radionuclides | Minimum Quantity | Type of Working Place or Laboratory Required | | | | |
|--------------------------------|---------------------|----------------------------------------------|---------------------------------------|-------------------------------|--|--|
| | μ Ci | Type C | Type B | Type A | | |
| 1. VERY HIGH | 0.1 (3.7 kBq) | <10 μ Ci (<370 kBq) | 10 μ Ci (370 kBq) | 10 μ Ci or more (>370 kBq) | | |
| 2. HIGH | 1.0 (37 kBq) | <100 μ Ci (<3.7 MBq) | 100 μ Ci (3.7 MBq) | 100 μ Ci or more (>3.7 MBq) | | |
| 3. MODERATE | 10 (370 kBq) | <1 mCi (<37 MBq) | 1 mCi - 1 Ci (37 MBq - 37 GBq) | 1 Ci or more (>37 GBq) | | |
| 4. LOW | 100 (3.7 MBq) | <10 mCi (<370 MBq) | 10 mCi - 10 Ci (370 MBq - 370 GBq) | 10 Ci or more (>370 GBq) | | |

APPENDIX L: FACILITIES AND EQUIPMENT CONSIDERATIONS

Below is a list of topics that should be considered when developing a description of the facilities and equipment that a licensee will use or otherwise have available. Not every applicant will need to address each topic in its application.

- Restricted areas are defined as areas to which access is limited by the licensee to protect individuals
 against undue risks from exposure to radiation and radioactive materials. The application should
 contain detailed descriptions and diagrams of the facilities, including information about the shielding
 properties of the construction materials used. Scaled drawings and sketches should be submitted
 showing the relationship between restricted areas and unrestricted areas and the location of all
 pertinent safety-related equipment.
- Bench top or open work areas may be used for sealed sources, for small quantities of solid materials in a form not likely to become airborne or dispersed, and for small quantities of liquids of such low volatility as not to cause airborne contamination or toxicity problems. Trays and/or absorbent surface covers to catch and retain spilled liquids should be used on these open work surfaces and inside closed systems discussed below. Surfaces should be smooth and non-porous, to facilitate decontamination.
- Radioactive materials that are handled or used in unsealed forms should be confined to control the
 release of material and to prevent the spread of contamination. Gaseous, volatile, and fine particulate
 solid materials should be handled in closed or isolated systems such as fume hoods or glove boxes
 with controlled, and possibly filtered, exhaust systems.

Chemical-type fume hoods provide a working area with controlled inward airflow from the room to the hood exhaust system. Hoods are used for gases, for unsealed volatile licensed materials, and for processes such as evaporation, that may release gases and vapors. Fume hoods provide emergency ventilation and exhaust for unplanned releases, such as accidental spills and ruptures, as well as routine exhaust of effluents. Filters may be required in the exhaust stream unless monitoring and/or calculations demonstrate that any planned or likely effluent will be in accordance with the limits found in **Chapter HFS 157 'Radiation Protection', Appendix E**.

Glove boxes are sealed boxes with transparent viewing windows, sealable ports or doors for transferring materials and equipment, and gloves sealed to the box through which licensed materials

are handled. Glove boxes are used for the containment during storage and use of liquids and solids that can become airborne particulates or aerosols. Glove boxes can be closed or exhausted, with filtration systems if appropriate, to prevent contamination.

- Sink faucets should be designed, where possible, for operation by foot, knee, or elbow rather than by hand.
- Plumbing and ductwork should be designed to avoid radioactive contamination build-up. This build-up of contamination can create external radiation exposure hazards and problems for decommissioning.
- Shielding consisting of lead or other high-density material in the form of bricks, panels, L-shields, storage containers, or other shapes may be used on bench tops, in fume hoods or in glove boxes to reduce radiation exposure from gamma-emitting radioactive materials. Similarly, shielding of low atomic number material, such as high-density plastic, may be used to reduce the exposure from high-energy beta-emitting materials. Shielded shipping containers are frequently used for continued storage after receipt of materials.
- A particular sink should be designated for disposal of liquid radioactive waste to the sanitary sewerage system. In some cases, depending on number of users and distance between areas of use, more than one sink may need to be designated.
- Labeled waste containers should be used. These containers may be shielded as necessary, placed near
 the waste-generating areas and away from areas frequently occupied by personnel. Additionally, these
 containers should be effectively enclosed to prevent airborne contamination from radioactive
 materials deposited.
- Remote handling tools, such as forceps or extension handles, should be used to provide distance in the
 handling of radioactive materials (ALARA). In addition, shielded handling devices, such as shielded
 syringes, can be used to protect workers from materials that cannot be handled remotely. Pipetting
 should be done using appropriate devices. Pipetting by mouth should be strictly forbidden.

- Where appropriate, ventilation systems should be designed, such that, in the event of an accident, they can be shut down and isolated to contain radioactivity.
- Designated areas should be provided for coats and personal belongings, to avoid contamination.
- Areas with the lowest possible background radiation levels should be designated for personnel dosimetry storage when not in use.
- Areas of use should be well lit to avoid spills and other accidents that could result in contamination build-up.
- Observation of activities conducted behind shielding with remote tools (or with extended arms and hands, within limits consistent with permissible occupational exposures) can be accomplished by mirrors, through shielded (e.g., leaded glass) windows, through transparent plastic beta shields, or by remote video monitoring.
- The combination of containment, shielding, and handling devices proposed for any use of radioactive materials should be appropriate to the type and quantity of materials to be used and to the type and duration of operations to be conducted.
- If respiratory protective equipment will be used to limit inhalation of airborne licensed material, follow the provisions of *HFS 157.27(1)*, *157.27(2)*, *157.27(3)*, *157.27(4)*, and *HFS 157.13(9)*.

APPENDIX M: AUDIT PROGRAM - NON-MEDICAL

The following audit form may be used by licensees to self-assess the adequacy of the licensed program, identify program weaknesses, and allow licensees to take early corrective actions (before a DHFS inspection). This form is not intended to be all-inclusive. During an audit, the auditor needs to keep in mind not only the requirements of **Chapter HFS 157 'Radiation Protection'**, but also the licensee's commitments in its applications and other correspondence with DHFS. Licensees are encouraged to modify the audit form as needed to include items specific to their licensed program. The auditor should also evaluate whether the licensee is maintaining exposures to workers and the general public as low as is reasonably achievable (ALARA) and, if not, make suggestions for improvement. References are included at the end of this audit form.

1. MANAGEMENT OVERSIGHT:

(Management support to radiation safety; RSC; RSO; program audits, including annual reviews of program and ALARA reviews; control by authorized users; appropriate follow up on events and previous audit/inspection findings)

2. AMENDMENTS AND PROGRAM CHANGES:

(Amendments to the license were properly implemented; if applicable, program and procedural changes were approved and implemented in accordance with license condition).

3. FACILITIES:

(Facilities as described in license; uses; control of access; engineering controls; calibration facilities; shielding; airflow)

4. EQUIPMENT AND INSTRUMENTATION:

(Operable and calibrated survey equipment; procedures)

5. MATERIAL USE, CONTROL, AND TRANSFER:

(Materials and uses authorized; security and control of licensed materials; and procedures for receipt and transfer of licensed material)

6. AREA RADIATION SURVEYS AND CONTAMINATION CONTROL:

(Radiological surveys; air sampling; leak tests; inventories; handling of radioactive materials; contamination controls; records; and public doses)

7. TRAINING AND INSTRUCTIONS TO WORKERS:

(Training and retraining requirements and documentation; interviews and observations of routine work; staff knowledge of all routine activities; **Chapter HFS 157 'Radiation Protection', subchapters III and X** requirements; emergency situations; and supervision by authorized users)

8. RADIATION PROTECTION:

(Radiation protection program with ALARA provisions; external and internal dosimetry; exposure evaluations; dose and survey records and reports; annual notifications to workers; information notices and other generic communications)

9. RADIOACTIVE WASTE MANAGEMENT:

(Disposal; effluent pathways and control; storage areas; transfer; packaging, control, and tracking procedures; equipment; incinerators, hoods, vents, and compactors; license conditions for special disposal method)

10. **DECOMMISSIONING:**

(Records relevant to decommissioning; decommissioning plan/schedule; notification requirements; cost estimates; funding methods; financial assurance; and Timeliness Rule requirements; changes in radiological conditions since decommissioning plan was submitted)

11. TRANSPORTATION:

(Quantities and types of licensed material shipped; packaging design requirements; shipping papers; hazardous materials (HAZMAT) communication procedures; return of sources; procedures for monitoring radiation and contamination levels of packages; HAZMAT training; and records and reports)

12. NOTIFICATIONS AND REPORTS:

(Reporting and follow-up of theft, loss, incidents and overexposures. Notifications of changes in RSO and/or authorized user. Radiation exposure reports provided to individuals.)

13. **POSTING AND LABELING:**

(License documents; **Chapter HFS 157 'Radiation Protection', Subchapters III and X**; Operating Procedures – Location of previous three documents may be posted on a notice; Notice to Employees; Emergency Procedures; Notices of violations; posting of radiation areas; and labeling of containers of licensed material)

14. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:

(Areas surveyed, both restricted and unrestricted, and measurements made; comparison of data with staff's results and rule)

15. AUDIT FINDINGS:

REFERENCES

A. MANAGEMENT OVERSIGHT

1. Radiation Safety Committee

Applicable license conditions.

2. Radiation Safety Officer

Applicable license conditions.

3. Audits, Reviews, or Inspections

HFS 157.21 Radiation protection programs.

HFS 157.31(2) Records of radiation protection programs.

Applicable license conditions.

4. ALARA

HFS 157.21 Radiation protection programs.

5. Authorized Users

Applicable license conditions.

B. AMENDMENTS AND PROGRAM CHANGES:

Applicable license conditions.

C. FACILITIES

1. Access Control

HFS 157.26(1)(2) Control of access to high / very high radiation areas.

HFS 157.28(1)(a) Security of stored material.

 $HFS\ 157.28(1)(b)$ Control of material not in storage.

Applicable license conditions.

2. Engineering Controls

HFS 157.21 Radiation protection programs.

HFS 157.27(1) Use of process or other engineering controls.

Applicable license conditions.

D. EQUIPMENT AND INSTRUMENTATION

1. Survey Instruments

HFS 157.25(1) General.

HFS 157.27(1) Use of Process or Other Engineering Controls.

HFS 157.31(3) Records of Surveys.

Applicable license conditions.

E. MATERIAL USE, CONTROL, AND TRANSFER

1. License and Applicable License Conditions.

2. Security and Control

HFS 157.03 Definitions (restricted area and unrestricted area).

HFS 157.28(1)(a) Security of stored material.

 $HFS\ 157.28(1)(b)$ Control of material not in storage.

3. Receipt and Transfer of Licensed Material

HFS 157.23(2) Compliance with dose limits for individual members of the public.

HFS 157.29(6) Procedures for receiving and opening packages.

HFS 157.25(1) Surveys.

HFS 157.31(3) Records of surveys.

HFS 157.13(15) Transfer of radioactive material.

HFS 157.06(1) Records of receipt and transfer.

HFS 157.13(18) Receipt, transfer, disposal records.

F. AREA RADIATION SURVEYS AND CONTAMINATION CONTROL

1. Area Surveys

HFS 157.23(2) Compliance with dose limits for individual members of the public.

HFS 157.25(1) General.

HFS 157.31(3) Records of surveys.

HFS 157.31(8) Records of dose to individual members of the public.

Applicable license conditions.

2. Leak Tests and Inventories

HFS 157.24 Testing for leakage or contamination of sealed sources.

Applicable license conditions.

G. TRAINING AND INSTRUCTIONS TO WORKERS

1. General

HFS 157.88(2) Instruction to workers

Knowledge of **HFS** Radiation protection procedures and requirements.

157 Subchapter III

Applicable license conditions.

H. RADIATION PROTECTION

- 1. Radiation Protection Program
 - a. Exposure evaluation

HFS 157.25(1) General.

b. Programs

HFS 157.21 Radiation protection programs.

- 2. Dosimetry
 - a. Dose Limits

HFS 157.22(1) Occupational dose limits for adults.

HFS 157.22(2) Compliance with requirements for summation of external and

internal doses.

HFS 157.22(7) Occupational dose limits for minors.

HFS 157.22(8) Doses to an embryo/fetus.

b. External

HFS 157.22(3) Determination of external dose from airborne radioactive material.

HFS 157.25(1) General.

HFS 157.25(2) Conditions requiring individual monitoring of external and internal

occupational dose.

Applicable license conditions.

c. Internal

HFS 157.22(4) Determination of internal exposure.

HFS 157.25(2) Conditions requiring individual monitoring of external and internal

occupational dose.

HFS 157.27 Respiratory protection and controls to restrict internal exposure in

restricted areas.

3. Records

HFS 157.31(2) Records of radiation protection programs.

HFS 157.31(3) Records of surveys.

HFS 157.22(5) & Determination of prior occupational dose.

HFS 157.31(5)

HFS 157.31(7) Records of individual monitoring results.

I. RADIOACTIVE WASTE MANAGEMENT

1. Disposal

HFS 157.29(4) Labeling containers.

HFS 157.30(1) General requirements.

HFS 157.31(3) Records of surveys.

HFS 157.31(9) Records of waste disposal.

HFS 157.30(3) Disposal by release into sanitary sewerage.

2. Effluents

a. General

Applicable license conditions

b. Release to septic tanks

HFS 157.03 Definitions (sanitary sewerage).

HFS 157, Appendix E, Table 2 Effluent Concentrations.

c. Incineration of waste

HFS 157.30(4) Treatment or disposal by incineration.

d. Control of air effluents and ashes

HFS 157.22(1) Occupational dose limits for adults.

HFS 157.23(1) Dose limits for individual members of the public.

HFS 157.25(1) General.

HFS 157.27(1) Use of process or other engineering controls.

Applicable license conditions

3. Waste Management

a. General

HFS 157.30(1) General requirements.

NRC Information Notice (IN) 90-09 "Extended Interim Storage of Low-Level Radioactive Waste by Fuel Cycle and Materials Licensees".

b. Waste compacted

Applicable license conditions.

c. Waste storage areas

HFS 157.28(1)(a) Security of stored material.

HFS 157.29(2) Posting requirements.

HFS 157.29(4) Labeling containers.

Applicable license conditions.

d. Packaging, Control, and Tracking

HFS 157.30(6) Transfer for disposal and manifests.

e. Transfer

HFS 157.30(1) General requirements.

HFS 157.30(6) Transfer for disposal and manifests.

f. Records

HFS 157.31(3) Records of surveys.

HFS 157.31(9) Records of waste disposal.

J. DECOMMISSIONING

HFS 157.15 Financial assurance and recordkeeping for Decommissioning.

HFS 157.13(11) Expiration and termination of licenses and decommissioning of

sites and separate buildings or outdoor areas.

K. TRANSPORTATION

1. General

HFS 157.92(3) Transportation of licensed material.

- 2. Shippers Requirements for Shipments and Packaging
 - a. General Requirements

49 CFR Part 173, Class 7 (radioactive) materials

Subpart I

49 CFR 173.24 General requirements for packaging and packages.

49 CFR 173.448 General transportation requirements

49 CFR 173.435 Table of A1 and A2 values for radionuclides

b. Transport Quantities

HFS 157.03 Definitions.

i. All quantities

HFS 157.03 Definitions.

49 CFR 173.410 General design requirements.

49 CFR 173.431 Activity limits Type A and Type B

| 49 CFR 173.441 | Radiation level limitations. |
|----------------------------------|--------------------------------------------------------------------------------------------------------------------------------|
| 49 CFR 173.443 | Contamination control. |
| 49 CFR 173.475 | Quality control requirements prior to each shipment of Class 7 (radioactive) materials. |
| 49 CFR 173.476 | Approval of special form Class 7 (radioactive) materials. |
| ii. Limited quantities | |
| 49 CFR 173.421 | Excepted packages for limited quantities of Class 7 (radioactive) materials. |
| 49 CFR 173.422 | Additional requirements for excepted packages containing Class 7 (radioactive) materials. |
| iii. Type A quantities | |
| 49 CFR 173.412 | Additional design requirements for Type A packages. |
| 49 CFR 173.415 | Authorized Type A packages. |
| 49 CFR 178.350 Specification 7A; | General packaging, Type A. |
| iv. Type B quantities | |
| 49 CFR 173.416 | Authorized Type B packages |
| 49 CFR 173.467 | Package testing |
| v. LSA material and SCO | |
| 49 CFR 173.403 | Definitions. |
| 49 CFR 173.427 | Transport requirements for low specific activity (LSA) Class 7 (radioactive) materials and surface contaminated objects (SCO). |
| c. HAZMAT Communication | Requirements |
| 49 CFR 172.200-205 | Shipping papers. |
| 49 CFR 172.300-338 | Marking. |
| 49 CFR 172.400-450 | Labeling. |
| 49 CFR 172.500-560 | Placarding. |
| 49 CFR 172.600-604 | Emergency response information. |
| 3. HAZMAT Training | |
| 49 CFR 172.702 | Applicability and responsibility for training and testing. |
| 49 CFR 172.704 | Training requirements. |
| 4. Transportation by Public High | way |

4. Transportation by Public Highway

49 CFR 171.15 Immediate notice of certain hazardous materials incidents. 49 CFR 171.16 Detailed hazardous materials incident reports.
 49 CFR 177.800 Purpose and scope of this part and responsibility for compliance and training.
 49 CFR 177.816 Driver training.
 49 CFR 177.842 Class 7 (radioactive) material.

L. NOTIFICATIONS AND REPORTS

HFS 157.88(3) Notifications and reports to individuals.
 HFS 157.32(1) Reports of theft or loss of licensed material.
 HFS 157.32(2) Notification of incidents.
 HFS 157.32(3) Reports of exposures, radiation levels, and concentrations of radioactive material exceeding the constraints or limits.
 HFS 157.13(17) Reporting requirements.

M. POSTING AND LABELING

| HFS 157.88(1) | Posting of notices to workers. |
|---------------|--------------------------------------|
| HFS 157.88 | Posting requirements. |
| HFS 157.29(2) | Posting requirements. |
| HFS 157.29(3) | Exemptions to posting requirements. |
| HFS 157.29(4) | Labeling containers. |
| HFS 157.29(5) | Exemptions to labeling requirements. |

APPENDIX N: REPORTING REQUIREMENTS

Table 7: DHFS Notifications and/or Reports

| Event | Telephone Notification | Written Report | Regulatory Requirement |
|-------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|-------------------|--------------------------------------|
| Theft or loss of material | Immediate | 30 days | HFS 157.32(1) |
| Whole body dose greater than 0.25 Sv (25 rems) | Immediate | 30 days | HFS 157.32(2)(a)(1) HFS 157.32(3) |
| Extremity dose greater than 2.5 Sv (250 rems) | Immediate | 30 days | HFS 157.32(2)(a) HFS 157.32(3) |
| Whole body dose greater than 0.05 Sv (5 rems) in 24 hours | 24 hours | 30 days | HFS 157.32(2)(b) HFS 157.32(3) |
| Extremity dose greater than 0.5 Sv (50 rems) in 24 hours | 24 hours | 30 days | HFS 157.32(2)(b) HFS 157.32(3) |
| Whole body dose greater than 0.05 Sv (5 rems) | None | 30 days | HFS 157.32(3) |
| Dose to individual member of public greater than 1 mSv (100 mrems) | None | 30 days | HFS 157.32(3) |
| Event that prevents immediate protective actions necessary to avoid exposure to radioactive materials that could exceed regulatory limits | Immediate | 30 days | HFS 157.13(17)(a) |
| Equipment is disabled or fails to function as designed when required to prevent radiation exposure in excess of regulatory limits | 24 hours | 30 days | HFS 157.13(17)(b) |
| Unplanned fire or explosion that affects the integrity of any licensed material or device, container, or equipment with licensed material | 24 hours | 30 days | HFS 157.13(17)(b)4 |

Note: Telephone notifications shall be made to DHFS at (608) 267-4797 during normal business hours (8 a.m. – 4:30 p.m.).

DHFS's 24 hour emergency telephone number is (608) 258-0099. Identify the emergency as radiological.

APPENDIX 0:

INSTRUMENT SPECIFICATIONS AND SURVEY INSTRUMENT AND AIR SAMPLER CALIBRATION PROGRAMS

Radiation Monitoring Instrument Specifications

The specifications in **Table 7** will help applicants and licensees choose the proper radiation detection equipment for monitoring the radiological conditions at their facility(ies).

 $\begin{tabular}{ll} Table 7 Typical Survey Instruments 1 (instruments used to measure radiological conditions at licensed facilities). \end{tabular}$

| Portable Instruments Used for Contamination and Ambient Radiation Surveys | | | | |
|---------------------------------------------------------------------------|----------------------|------------------------------------------------|------------|--|
| Detectors | Radiation | Energy Range | Efficiency | |
| Exposure Rate Meters | Gamma, X-ray | μR-R | N/A | |
| Count Rate Meters | | | | |
| GM | Alpha | All energies (dependent on window thickness) | Moderate | |
| | Beta | All energies (dependent on window thickness) | Moderate | |
| | Gamma | All energies | < 1% | |
| NaI Scintillator | Gamma | All energies (dependent on crystal thickness) | Moderate | |
| Plastic Scintillator | Beta | C-14 or higher (dependent on window thickness) | Moderate | |
| Stationary Instrum | ents Used to Measure | e Wipe, Bioassay, and Effluer | nt Samples | |
| Detectors | Radiation | Energy Range | Efficiency | |
| LSC* | Alpha | All energies | High | |
| | Beta | All energies | High | |
| | Gamma | | Moderate | |
| Gamma Counter (NaI)* | Gamma | All energies | High | |
| Gas Proportional | Alpha | All energies | High | |
| | Beta | All energies | Moderate | |
| | Gamma | All energies | < 1% | |

¹ Table from The Health Physics & Radiological Health Handbook, Revised Edition, edited by Bernard Shleien, 1992 (except for * items).

Instrument Calibration Program

Training

Before allowing an individual to perform survey instrument calibrations, the RSO will ensure that he or she has sufficient training and experience to perform independent survey instrument calibrations.

Classroom training may be in the form of lecture, videotape, or self-study and will cover the following subject areas:

- Principles and practices of radiation protection
- Radioactivity measurements, monitoring techniques, and using instruments
- Mathematics and calculations basic to using and measuring radioactivity
- Biological effects of radiation.

Appropriate on-the-job-training consists of the following:

- Observing authorized personnel performing survey instrument calibration
- Conducting survey meter calibrations under the supervision and in the physical presence of an individual authorized to perform calibrations.

Facilities and Equipment for Calibration of Dose Rate or Exposure Rate Instruments

- To reduce doses received by individuals not calibrating instruments, calibrations will be conducted in an isolated area of the facility or at times when no one else is present.
- Individuals conducting calibrations will wear assigned dosimetry.
- Individuals conducting calibrations will use a calibrated and operable survey instrument to ensure that unexpected changes in exposure rates are identified and corrected.

Procedure for Calibrating Survey Instruments

A radioactive sealed source(s) used for calibrating survey instruments will:

- Approximate a point source
- Approximate the same energy and type of radiation as the environment in which the calibrated device will be employed

• For dose rate and exposure rate instruments, the source should be strong enough to give an exposure rate of at least about 7.7 x 10⁻⁶ coulombs/kilogram/hour (30 mR/hr) at 100 cm [e.g., 3.1 gigabecquerels (85 mCi) of cesium-137 or 7.8 x 10² megabecquerels (21 mCi) of cobalt-60

The three kinds of scales frequently used on dose or dose rate survey meters are calibrated as follows:

- Linear readout instruments with a single calibration control for all scales shall be adjusted at the point recommended by the manufacturer or at a point within the normal range of use. Instruments with calibration controls for each scale shall be adjusted on each scale. After adjustment, the response of the instrument shall be checked at approximately 20% and 80% of full scale. The instrument's readings shall be within \pm 15% of the conventionally true values for the lower point and \pm 10% for the upper point.
- Logarithmic readout instruments, which commonly have a single readout scale spanning several decades, normally have two or more adjustments. The instrument shall be adjusted for each scale according to site specifications or the manufacturer's specifications. After adjustment, calibration shall be checked at a minimum of one point on each decade. Instrument readings shall have a maximum deviation from the conventionally true value of no more than 10% of the full decade value.
- Meters with a digital display device shall be calibrated the same as meters with a linear scale.
- Readings above 2.58 x 10⁻⁴ coulomb/kilogram/hour (1 R/hr) need not be calibrated, but such scales should be checked for operation and response to radiation.
- The inverse square and radioactive decay law should be used to correct changes in exposure rate due to changes in distance or source decay.

Surface Contamination Measurement Instruments

- Survey meters' efficiency must be determined by using radiation sources with similar energies and types of radiation that the survey instrument will be used to measure.
- If each scale has a calibration potentiometer, the reading shall be adjusted to read the conventionally true value at approximately 80% of full scale, and the reading at approximately 20% of full scale shall be observed. If only one calibration potentiometer is available, the reading shall be adjusted at mid-scale on one of the scales, and readings on the other scales shall be observed. Readings shall be within ±20% of the conventionally true value.

Procedures for Calibrating, Liquid Scintillation Counters, Gamma Counters, Gas Flow Proportional Counters, and Multichannel Analyzers

A radioactive sealed source used for calibrating instruments will do the following:

- Approximate the geometry of the samples to be analyzed
- Approximate the same energy and type of radiation as the samples that the calibrated device will be used to measure.

Calibration

- Calibration must produce readings within \pm 20% of the actual values over the range of the instrument.
- Calibration of liquid scintillation counters will include quench correction.

Calibration Records

Calibration records, for all survey instruments, should indicate the procedure used and the data obtained. The description of the calibration should include:

- The owner or user of the instrument
- A description of the instrument, including the manufacturer's name, model number, serial number, and type of detector
- A description of the calibration source, including the exposure rate at a specified distance or activity on a specified date
- For each calibration point, the calculated exposure rate or count rate, the indicated exposure rate or count rate, the deduced correction factor (the calculated exposure rate or count rate divided by the indicated exposure rate or count rate), and the scale selected on the instrument
- For instruments with external detectors, the angle between the radiation flux field and the detector (i.e., parallel or perpendicular)
- For instruments with internal detectors, the angle between radiation flux field and a specified surface of the instrument
- For detectors with removable shielding, an indication whether the shielding was in place or removed during the calibration procedure

- The exposure rate or count rate from a check source, if used
- The name of the person who performed the calibration and the date it was performed.

The following information will be attached to the instrument as a calibration sticker or tag:

- For exposure rate meters, the source isotope used to calibrate the instrument (with correction factors) for each scale
- The efficiency of the instrument, for each isotope the instrument will be used to measure (if efficiency is not calculated before each use)
- For each scale or decade not calibrated, an indication that the scale or decade was checked only for function but not calibrated
- The date of calibration and the next calibration due date
- The apparent exposure rate or count rate from the check source, if used.

Air Sampler Calibration

In order to assess accurately the air concentration of radioactive materials in a given location, the volume of air sampled and the quantity of contaminant in the sample must be determined. Accurate determination of the volume of air sampled requires standard, reproducible, and periodic calibration of the air metering devices that are used with air sampling instruments.

The publication entitled "Air Sampling Instruments" found in the 7th Edition, American Conference of Governmental Industrial Hygienists, 1989, provides guidance on total air sample volume calibration methods acceptable to DHFS staff, as supplemented below.

Frequency of Calibration

- A licensee committed to a routine or emergency air sampling program should perform an
 acceptable calibration of all airflow or volume metering devices at least annually (See NRC
 Regulatory Guide 8.25).
- Special calibrations should be performed at any time there is reason to believe that the operating characteristics of a metering device have been changed, by repair or alteration, or whenever system performance is observed to have changed significantly.
- Routine instrument maintenance should be performed as recommended by the manufacturer.

 Primary or secondary standard instruments used to calibrate air sampling instruments should be inspected frequently for consistency of performance.

Error Limit For Measurement of Air Sample Volume

Most methods of calibrating airflow or air volume metering devices require direct comparison to a primary or secondary standard instrument, to determine a calibration curve or a correction factor. An example of a primary standard is a spirometer that measures total air volume directly with high precision by liquid displacement. An example of a secondary standard is a wet-test meter that has been calibrated against a primary standard.

The following are significant errors associated with determining the total air volume sampled:

E_C: The error in determining the calibration factor. (An acceptable estimate is the percentage error associated with the standard instrument used in the calibration.)

E_S: Intrinsic error in reading the meter scale. (An acceptable estimate is the percentage equivalent of one-half of the smallest scale division, compared to the scale reading.)

E_t: The percentage error in measurement of sampling time that should be kept within 1%.

E_V: The most probable value of the cumulative percentage error in the determination of the total air volume sampled. E_V can be calculated from the following equation, provided there are no additional significant sources of errors:

$$E_V = [{E_S}^2 + {E_C}^2 + {E_t}^2]^{1/2}$$

The most probable value of the cumulative error E_V , in the determination of total volume, should be less than 20%.

A sample calculation of the most probable value of the cumulative error in total volume measured is as follows:

If accuracies of the scale reading, the calibration factor, and sample time are \pm 4, 2, and 1%, respectively, and there are no other significant sources of error, the cumulative error would be:

$$E_V = [4^2 + 2^2 + 1^2]^{1/2} = 4.58\%$$
 or approx. 5%

If there are significant differences in pressure and temperature between the calibration site and the sampling site, appropriate corrections should be made using the ideal gas laws provided below:

 $V_S = V_1 * (P_1/760) * (273/T_1)$

where V_s = volume at standard pressure and temperature (760 mm Hg and 273K)

 V_1 = volume measured at conditions P_1 and T_1

 T_1 = temperature of V_1 in K

 P_1 = pressure of V_1 in mm Hg

Documentation of Calibration of Air Metering Devices

The licensee should maintain records of all routine and special calibrations of airflow or volume metering devices, including the primary or secondary standard used, method employed, and estimates of accuracy of the calibrated metering devices. All instruments should be clearly labeled as to the date and results of the most recent calibration and should include the appropriate correction factors to be used.

References:

- 1. NRC NUREG 1556 Vol. 18, "Program-Specific Guidance about Service Provider Licenses", November 2000.
- 2. NRC Regulatory Guide 8.25, Revision 1, "Air Sampling in the Workplace," June 1992.
- 3. NRC NUREG-1400, "Air Sampling in the Workplace," September 1993.
- 4. *The Health Physics & Radiological Health Handbook, 3rd Ed.* Edited by Bernard Shleien, Lester A. Slaback, Jr., and Brian Kent Birky, 1998.
- 5. ANSI N323A-1997, "Radiation Protection Instrumentation Test and Calibration, Portable Survey Instruments." Copies may be ordered electronically at the following address: http://www.ansi.org or obtained by contacting the American National Standards Institute, 25 West 43rd Street Fourth Floor, New York, New York 10036, Phone: 212.642.4900, Fax: 212.398.0023.
 - 6. "Air Sampling Instruments," American Conference of Governmental Industrial Hygienists, 7th Edition, 1989.
- 7. DOE G 441.1-7, "Portable Monitoring Instrument Calibration Guide," U.S. Department of Energy, March 1999.
- 8. DOE G 441.1-8, "Air Monitoring Guide," U.S. Department of Energy," March 1999.

APPENDIX P:

MATERIAL RECEIPT AND ACCOUNTABILITY

Sample Procedure for Ordering and Receiving Radioactive Material

- The RSO should approve or place all orders for radioactive material and should ensure that the requested material, quantities, manufacturer, and model are authorized by the license and that the possession limits are not exceeded.
- During normal working hours, carriers should be instructed to deliver radioactive packages directly to the Radiation Safety Office (or designated receiving area).
- During off-duty hours, security or other designated trained personnel should accept delivery of radioactive packages in accordance with the procedure outlined in the sample memorandum below:

Sample Memorandum

Memorandum for Security Personnel

From: RSO, President, Vice President, etc.

Subject: Procedures for Receipt of Packages Containing Radioactive Material

If the package appears to be damaged, immediately contact the RSO. Ask the carrier to remain at the facility until it can be determined that neither the carrier nor the vehicle is contaminated.

Any packages containing radioactive material that arrive between (state times, e.g., 4:30 p.m. and 7:00 a.m. or on Saturdays or Sundays) shall be signed for by the security guard (or other designated trained individual) on duty and taken immediately to the designated receiving area. Security personnel (or other designated trained individual) should unlock the door, place the package in the designated secured storage area, and re-lock the door.

| Radiation Safety Officer (RSO): _ | |
|-----------------------------------|------|
| Office Phone: | |
| Home Phone: | |

Sample Instructions to Personnel Involved in Material Receipt

Shipping and Receiving Personnel

During normal working hours, immediately upon receipt of any package of licensed material, each package must be visually inspected for any signs of shipping damage, such as crushed or punctured containers or signs of dampness. Any obvious damage must be reported to the RSO immediately. Do not touch any package suspected of leaking. Request the person delivering the package to remain until monitored by the RSO.

Outside of normal working hours (e.g., nights, weekends, and holidays), deliveries will usually be handled by security personnel (or other trained individuals), as described in the above procedures. Since certain packages of licensed material will have detectable external radiation, they should be sent immediately to a designated storage area, where they will be checked for contamination and external radiation level as soon as practical. They should not be allowed to remain in the receiving area any longer than necessary, as they may be a source of exposure for receiving personnel.

If the instructions are not clear, or if there are questions regarding receiving packages containing radioactive material, please contact:

| Name | | | |
|-------|--|--|--|
| | | | |
| | | | |
| Phone | | | |

For additional information on worker training, see the section entitled "Training for Individuals Working In or Frequenting Restricted Areas".

Materials Possessed Under a General License, or Received from a General Licensee

Individuals at your facility may receive and use material pursuant to a general license as authorized in HFS 157.11. Generally licensed materials are distributed by manufacturers authorized by DHFS, the NRC or an Agreement State to distribute materials directly to the persons who will use them under a general license. Some common items include nickel-63 sources in electron capture detectors in certain gas chromatographs, tritium gas contained in self-luminous EXIT signs, calibration sources in liquid scintillation counters, and uranyl acetate used for staining electron microscope samples. You should develop a policy for how your institution will require responsible use and tracking of this material.

Generally licensed material may also be received when a general licensee transfers a generally licensed item to a specific license that is authorized to possess the material. However, when received by the specific licensee (your facility), the item must now be considered as specifically licensed and should be tracked with other specifically licensed material.

Sample Procedure for Safely Opening Packages Containing Licensed Materials

For packages received under the specific license, authorized individuals shall implement procedures for opening each package, as follows:

- Wear gloves to prevent hand contamination.
- Visually inspect the package for any sign of damage (e.g. crushed, punctured). If damage is noted, stop and notify the RSO.
- Check DOT White I, Yellow II, or Yellow III label or packing slip for activity of contents, so shipment does not exceed license possession limits.
- Monitor the external surfaces of a labeled package according to specifications in HFS 157.29(6)(b).
- Open the outer package (following supplier's directions if provided) and remove packing slip.
 Open inner package to verify contents (compare requisition, packing slip and label on the bottle or other container). Check integrity of the final source container (e.g., inspecting for breakage of seals or vials, loss of liquid, discoloration of packaging material, high count rate on smear). Check again that the shipment does not exceed license possession limits. If you find anything other than expected, stop and notify the RSO.

- Survey the packing material and packages for contamination before discarding. If contamination is
 found, treat as radioactive waste. If no contamination is found, obliterate the radiation labels prior
 to discarding in the regular trash.
- Maintain records of receipt, package survey, and wipe test results.
- Notify the final carrier and, by telephone, and either telegram, or facsimile, the Department of
 Health and Family Services, when removable radioactive surface contamination exceeds the limits
 of *HFS 157.94(1)(h)*; or external radiation levels exceed the limits of *HFS 157.94(1)(i)*.

Sample Transfer Policy Statements

Internal Transfers

Licensed materials that may be transferred from one department or laboratory or AU's control to another should have prior approval from the RSO. A written transfer procedure should be developed by the RSO to ensure that transfers are done in accordance with the conditions of the license. All transfers shall be done in a way that minimizes the probability of spillage or breakage. Double containers should be used, including suitable shielding, for such transfers.

External Transfers

Licensed material shall not be transferred or shipped from one institution to another without the approval of the RSO. Such transfers/shipments must be packaged and labeled in accordance with DOT, DHFS, NRC, or U.S. Postal Service Regulations, whichever is applicable.

Gifts

On occasion, licensees may be offered or have donated licensed materials by other individuals as gifts (e.g., a retiring medical practitioner donating his cesium needles to the university medical center). All such gifts of radioactive materials must be transferred to the licensee and handled in accordance with DHFS requirements and the conditions of the license. In any case, the RSO should approve the gift prior to the transfer.

References:

1. DOE G 441.13-1, "Sealed Radioactive Source Accountability and Control", U.S. Department of Energy," April 1998.

Appendix Q:

Methodology for Determining Public Dose

This appendix describes methods for determining radiation doses to members of the public.

Licensees must ensure that:

- The radiation dose received by individual members of the public does not exceed 1 millisievert (mSv) [100 millirem (mrem)] in one calendar year resulting from the licensee's possession and/or use of licensed materials.
- The radiation dose in unrestricted areas does not exceed 0.02 mSv (2 mrem) in any one hour.
- Air emissions of radioactive materials do not result in doses greater than 0.1 mSv (10 mrem) TEDE.

Members of the public include persons who live, work, study, or may be near locations where radioactive material is used or stored and employees whose assigned duties do not include the use of radioactive material but may work in the vicinity where such materials are used or stored.

Doses to Members of the Public

INCLUDES doses from:

- Radiation and/or radioactive material released by a licensee
- Sources of radiation under the control of a licensee
- Air effluents from sources of licensed radioactive materials
- Licensed material in transportation or storage at the licensee's facility

DOES NOT INCLUDE doses from:

- Sanitary sewerage discharges from licensees
- Natural background radiation
- Medical administration of radioactive material
- Voluntary participation in medical research

Typical unrestricted areas may include offices, shops, laboratories (where licensed material is not used or stored), areas outside buildings, property, and storage areas. The licensee does not control access to these areas for purposes of controlling exposure to radiation or radioactive materials, but the licensee may control access to these areas for other reasons, such as security.

The licensee may show compliance with the annual dose limit for individual members of the public by:

- Demonstrating by measurement or calculation that the TEDE to the individual likely to receive the highest dose at the boundary of the unrestricted area does not exceed 1 mSv (100 mrem).
- Demonstrating that the annual average concentration of radioactive material released in gaseous and liquid effluents at the boundary of the unrestricted area does not exceed the values specified in **Table 2 of Appendix E of HFS 157**; and if an individual were continuously present in an

unrestricted area, the dose from external sources would not exceed 0.02 mSv (2 mrem) in an hour and 0.5 mSv (0.05 rem) in a year.

In order to perform a dose assessment, the licensee should identify all potential sources of external and internal radiation exposure to members of the public and all locations of use, transport, and storage of radioactive material at the facility. The licensee must then take radiation measurements or perform calculations to demonstrate compliance.

Measurements

The licensee may use measurements to demonstrate that the average annual releases are within regulatory limits, as well as to demonstrate that the TEDE to the individual likely to receive the highest dose at the boundary of the unrestricted area does not exceed 1 mSv (100 mrem). These measurements may include:

- Dose rate surveys for radiation exposures from external radiation sources.
- Measurements of radionuclides in air and water effluent.

The method used to measure dose will depend on the nature of the radiation source. If the source of radiation is constant, it may be adequate to measure the dose rate and integrate it over time. If the source of radiation differs or changes over time, it may be necessary to perform continuous measurements.

Radioactivity releases may be determined by effluent monitoring or by effluent sampling and analysis. Airborne effluents may be discharged when volatile materials are used, such as during iodinations, but the discharge itself is usually not continuous since volatile materials are often used periodically rather than continuously. Liquid effluents may be discharged continuously or may be stored and subsequently discharged on a batch basis. For each type of source and for each route of potential exposure, consider the location of measurement points, whether continuous or periodic monitoring is required, the frequency of sampling and measurement, and any additional information. For discharges of airborne radionuclides, for example, it may be necessary to obtain information on the efficiency of filters and the air flow rate of the discharge system, as well as meteorological data and the distance to the nearest individual member of the public.

Calculation Method

Using a calculation method, the licensee must determine the highest dose an individual is likely to receive at the boundary of the unrestricted area. The licensee must take into account the individual's exposure from external sources and the concentration of radionuclides in gaseous and liquid releases. In practice, the licensee may wish to make conservative assumptions to simplify the dose calculation.

The public dose limit applies to the individual who is likely to receive the highest dose from licensed operations. Therefore, the dose calculations must consider the location with the potential for the highest internal and external exposures. An extremely conservative calculation would assume that the individual was continuously present 24 hours a day, 365 days a year, or an occupancy factor of 1 (see **Table 8**). If the result of the calculation using an occupancy factor of 1 demonstrates that the public dose limit is not exceeded, then there is no need for further evaluation.

If, however, the licensee would rather choose a more realistic assumption of the individual's occupancy at the points of highest internal and external exposures, then the licensee may use the occupancy factors in **Table 8** or may calculate a specific occupancy factor by determining the likely fraction of time that the individual is present.

Table 8: Standard Occupancy Factors

| Occupancy Factor | Description |
|-------------------------|---------------------------------------------------------------------------------------------------------------------------------------------|
| | Work areas such as offices, laboratories, shops, and occupied space in nearby buildings or outdoor areas |
| 1/4 | Corridors, lounges, elevators using operators, unattended parking lots |
| 1/1 n | Waiting rooms, rest rooms, stairways, unattended elevators, janitor's closets, outside areas used only for pedestrians or vehicular traffic |

Records

The licensee must maintain records to demonstrate compliance with the dose limit for individual members of the public, until DHFS terminates the license. In general, survey and monitoring records of ambient radiation and effluent radioactivity should be adequate.

Appendix R: General Topics for Safe Use of Radioisotopes And Emergency Procedures

General Topics for Safe Use of Radioisotopes

Each laboratory or area where radioactive material is used or stored should have general rules, so that workers know what is required. Typical instructions should include:

- Wear a laboratory coat or other protective clothing at all times in areas where licensed materials are used.
- Wear disposable gloves at all times when handling licensed materials.
- After each procedure or before leaving the area, monitor hands, shoes, and clothing for contamination in a low-background area.
- Do not eat, drink, smoke or apply cosmetics in any area where licensed material is stored or used.
- Do not store food, drink or personal effects in areas where licensed material is stored or used.
- Wear personnel monitoring devices, if required, at all times while in areas where licensed materials are used or stored.
- Dispose of radioactive waste only in designated, labeled and properly shielded receptacles.
- Never pipette by mouth.
- Store radioactive solutions in clearly labeled containers.
- Secure all licensed material when it is not under the constant surveillance and immediate control of the user(s).

Radionuclides-specific Procedures

Licensees should develop written procedures for use of different radionuclides so that users know the types of shielding, protective clothing, survey instruments, surveys, and decontamination activities that are required. Examples of such procedures are included below.

Example 1:

If requesting more than 37 MBq (1 mCi) of iodine-125 or iodine-131, special safety instructions should be provided to users, including the following:

- A mandatory radiation survey and wipe test for radioactive contamination after each use
- Bioassay procedures for individuals working with millicurie quantities of radioiodine
- The use of vented hoods for iodination and for the storage of millicurie quantities of radioiodine
- A dry run prior to the performance of unfamiliar procedures, in order to preclude unexpected complications. In addition, it is recommended that the RSO be present during new procedures.
- Procedures for measuring the concentration of radioiodine effluents from the hoods.

Example 2:

If requesting more than 37 MBq (1 mCi) of phosphorus-32, special safety instructions should be provided to users, including the following:

- The use of low-density plastic shielding in order to keep bremsstrahlung radiation to a minimum
- A mandatory radiation survey and wipe test for radioactive contamination after each use
- The use of extremity monitors for procedures that involve one millicurie or more
- A dry run prior to the performance of unfamiliar procedures, in order to preclude unexpected complications. In addition, it is recommended that the RSO be present during new procedures
- The use of eye protection for procedures that involve 10 millicuries or more.

Procedures for Handling Emergencies

General Safety Procedures to Handle Spills

- Name and telephone number of RSO or an alternate person(s) should be posted conspicuously in areas of use, so that it is readily available to workers in case of emergencies. Licensee should have emergency equipment readily available for handling spills. Spill kits should include the following:
- Disposable gloves
- Housekeeping gloves
- Disposable lab coats
- Disposable head coverings
- Disposable shoe covers

- Roll of absorbent paper with plastic backing
- Masking tape
- Plastic trash bags with twist ties
- "Radioactive Material" labeling tape
- Marking pen
- Pre-strung "Radioactive Material" labeling tags
- Box of Wipes
- Instructions for "Emergency Procedures"
- Clipboard with a copy of the Radioactive Spill Report Form for the facility
- Pencil
- Appropriate survey instruments, including batteries (for survey meters).

The decision to implement a major spill procedure instead of a minor spill procedure depends on many incident specific variables, such as the number of individuals affected; other hazards present; the likelihood of spread of contamination; and types of surfaces contaminated as well as the radiotoxicity of the spilled material. For some spills of short-lived radionuclides, the best spill procedure may be restricted access pending complete decay. The applicant should establish criteria for determining when the major spill procedure and minor spill procedure should be utilized.

Minor Spills of Liquids and Solids

• Instructions to Workers

- Notify persons in the area that a spill has occurred.
- Prevent the spread of contamination by covering the spill with absorbent paper. (Paper should be dampened if solids are spilled.)
- Clean up the spill, wearing disposable gloves and using absorbent paper.
- Carefully fold the absorbent paper with the clean side out and place in a plastic bag for transfer to a radioactive waste container. Put contaminated gloves and any other contaminated disposable material in the bag.
- Survey the area with an appropriate low-range radiation detector survey meter or other appropriate technique. Check the area around the spill for contamination. Also check hands, clothing, and shoes for contamination.
- Report the incident to the Radiation Safety Officer (RSO) promptly.
- Allow no one to return to work in the area unless approved by the RSO.
- Cooperate with the RSO and/or the RSO's staff (e.g., investigation of root cause, provision

- of requested bioassay samples).
- Follow the instructions of the RSO and/or the RSO's staff (e.g., decontamination techniques, surveys, provision of bioassay samples, requested documentation).

· Reminders to RSO

- Follow up on the decontamination activities and document the results.
- As appropriate, determine cause and corrective actions needed; consider bioassays, if there is a potential for internal contamination.
- If necessary, notify DHFS.

Major Spills of Liquids and Solids

· Instructions to Workers

- Clear the area. If appropriate, survey all persons not involved in the spill and vacate the room.
- Prevent the spread of contamination by covering the spill with absorbent paper (paper should be dampened, if solids are spilled), but do not attempt to clean it up. To prevent the spread of contamination, limit the movement of all personnel who may be contaminated.
- Shield the source only if it can be done without further contamination or significant increase in radiation exposure.
- Close the room and lock or otherwise secure the area to prevent entry. Post the room with a sign to warn anyone trying to enter that a spill of radioactive material has occurred.
- Notify the RSO immediately.
- Survey all personnel who could possibly have been contaminated. Decontaminate personnel by removing contaminated clothing and flushing contaminated skin with lukewarm water and then washing with a mild soap.
- Allow no one to return to work in the area unless approved by the RSO.
- Cooperate with the RSO and/or the RSO's staff (e.g., investigation of root cause, provision of requested bioassay samples).
- Follow the instructions of the RSO and/or the RSO's staff (e.g., decontamination techniques, surveys, provision of bioassay samples, requested documentation).

· Reminders to RSO

- Confirm decontamination of personnel. If decontamination of personnel was not fully successful, consider inducing perspiration by covering the area with plastic. Then wash the affected area again to remove any contamination that was released by the perspiration.
- Supervise decontamination activities and document the results. Documentation should include location of surveys and decontamination results.

- Determine cause and needed corrective actions; consider need for bioassays if licensed material is suspected to have been ingested, inhaled, or absorbed through or injected under the skin.
- If necessary, notify DHFS.

Incidents Involving Radioactive Dusts, Mists, Fumes, Organic Vapors, and Gases

· Instructions to Workers

- Notify all personnel to vacate the room immediately.
- Shut down ventilation system, if possible, unless it is determined that the room ventilation system needs to be used to clear the air for access purposes.
- Vacate the room. Seal the area, if possible.
- Notify the RSO immediately.
- Ensure that all access doors to the area are closed and posted with radiation warning signs, or post guards (trained) at all access doors to prevent accidental opening of the doors or entry to the area.
- Survey all persons who could have possibly been contaminated. Decontaminate as directed by the RSO.
- Promptly report suspected inhalations and ingestions of licensed material to the RSO.
- Decontaminate the area only when advised and/or supervised by the RSO.
- Allow no one to return to work in the area unless approved by the RSO.
- Cooperate with the RSO and/or the RSO's staff (e.g., investigation of root cause, provision of requested bioassay samples).
- Follow the instructions of the RSO and/or the RSO's staff (e.g., decontamination techniques, surveys, provision and collection of bioassay samples, requested documentation).

· Reminders to RSO

- Supervise decontamination activities.
- Perform air sample surveys in the area before permitting resumption of work with licensed materials
- Provide written directions to potentially contaminated individuals about providing and collecting urine, breath, blood, or fecal samples, etc.
- Consider need for medical exam and/or whole body count before permitting involved individuals to return to work with licensed material.
- Determine cause and corrective actions needed; consider need for bioassays if licensed material is suspected to have been ingested, inhaled, or absorbed through or injected under the skin. Document incident.

- If necessary, notify DHFS.

Minor Fires

· Instructions to Workers

- Immediately attempt to put out the fire by approved methods (e.g., fire extinguisher) if other fire hazards or radiation hazards are not present.
- Notify all persons present to vacate the area and have one individual immediately call the RSO and fire department (as instructed by RSO).
- Once the fire is out, isolate the area to prevent the spread of possible contamination.
- Survey all persons involved in combating the fire for possible contamination.
- Decontaminate personnel by removing contaminated clothing and flushing contaminated skin with lukewarm water, then washing with a mild soap.
- In consultation with the RSO, determine a plan of decontamination and the types of protective devices and survey equipment that will be necessary to decontaminate the area.
- Allow no one to return to work in the area unless approved by the RSO.
- Cooperate with the RSO and/or the RSO's staff (e.g., investigation of root cause, provision of requested bioassay samples).
- Follow the instructions of the RSO and/or the RSO's staff (e.g., decontamination techniques, surveys, provision of bioassay samples, requested documentation).

· Reminders to RSO

- Supervise decontamination activities.
- If decontamination of personnel was not fully successful, consider inducing perspiration by covering the area with plastic. Then wash the affected area again to remove any contamination that was released by the perspiration.
- Consult with fire safety officials to assure that there are no other possibilities of another fire starting.
- Determine cause and needed corrective actions; consider need for bioassays if licensed material is suspected to have been ingested, inhaled, or absorbed through or injected under the skin. Document incident.
- If necessary, notify DHFS.

Fires, Explosions, or Major Emergencies

· Instructions to Workers

- Notify all persons in the area to leave immediately.
- Notify the fire department.
- Notify the RSO and other facility safety personnel.
- Upon arrival of firefighters, inform them where radioactive materials are stored or where radioisotopes were being used; inform them of the present location of the licensed material and the best possible entrance route to the radiation area, as well as any precautions to avoid exposure or risk of creating radioactive contamination by use of high pressure water, etc.
- Cooperate with the RSO and/or the RSO's staff (e.g., investigation of root cause, provision of requested bioassay samples).
- Allow no one to return to work in the area unless approved by the RSO.
- Follow the instructions of the RSO and/or the RSO's staff (e.g., decontamination techniques, surveys, provision of bioassay samples, requested documentation).

Reminders to RSO

- Coordinate activities with facility's industrial hygienist or environmental health & safety office, and with local fire department.
- Consult with the fire-fighting personnel and set up a controlled area where the firefighters can be surveyed for contamination of their protective clothing and equipment after the fire is extinguished.
- Once the fire is extinguished, advise the firefighters not to enter potentially contaminated areas or areas where radioactive sources may be present until a thorough evaluation and survey are performed to determine the extent of the damage to the licensed material use and storage areas.
- Perform thorough contamination surveys of the firefighters and their equipment before they leave the controlled area and decontaminate, if necessary.
- Supervise decontamination activities.
- Consider bioassays if licensed material is suspected to have been ingested, inhaled, or absorbed through or injected under the skin. Document incident.
- If necessary, notify DHFS.

Copies of emergency procedures should be provided to all users. Post a current copy in each laboratory or other area where radioactive material is used.

Procedures for Collecting Bioassay Samples

In the event of an emergency where an individual may become contaminated and radioactive material was taken into the body through skin absorption or other means, or is suspected of having ingested or inhaled radioactive material, an estimate of the amount of material taken into the body may be required. The following items should be considered in developing your procedures:

- the type of bioassay that must be performed (direct or indirect)
- the number of samples or data points to be collected
- the frequency of sampling (hourly, daily, weekly, once?, etc.)
- the size of the sample to be collected (24-hour urine collection?)
- the ease/difficulty of sample collection
- the need for written instructions to be provided to the sample collector, who may be the contaminated individual.

Appendix S:

Radiation Surveys

This Appendix provides applicants and licensees with additional information on surveys, including training requirements, survey frequency, contamination limits, and bioassays.

Training

Before allowing an individual to perform surveys, the RSO (or for Type C broad scopes, the individual designated as responsible for the day-to-day operation of the radiation safety program) will ensure that he or she has sufficient training and experience to perform surveys independently.

Didactic training may be in the form of lecture, videotape, or self-study and will cover the following subject areas:

- Principles and practices of radiation protection
- Radioactivity measurements, monitoring techniques, and using instruments
- Mathematics and calculations basic to using and measuring radioactivity
- Biological effects of radiation.

Appropriate on-the-job-training consists of the following:

- Observing authorized personnel using survey equipment, collecting samples, and analyzing samples
- Using survey equipment, collecting samples, and analyzing samples under the supervision and in the physical presence of an individual authorized to perform surveys.

Facilities and Equipment

- To ensure achieving the required sensitivity of measurements, survey samples will be analyzed in a low-background area.
- A gamma counter system with a single or multi-channel analyzer can be used to count samples containing gamma-emitters (e.g., cesium-137, cobalt-60).
- A liquid scintillation or gas-flow proportional counting system can be used to count samples
 containing alpha-emitters, beta-emitters, and gamma-emitters (if efficiency is great enough to
 achieve the required sensitivity for measurements).

Ambient Radiation Level Surveys

- Dose-rate surveys, at a minimum, should be performed in locations where workers are exposed to
 radiation levels that might result in radiation doses in excess of 10% of the occupational dose
 limits or where an individual is working in a dose rate of 0.025 mSv (2.5 mrem/hr) or more (50
 mSv/year divided by 2,000 hr/year).
- *HFS 157.23(1)* requires that the total effective dose equivalent to an individual member of the public from the licensed operation does not exceed 1 mSv (0.1 rem) in a year and the dose in any unrestricted area from external sources does not exceed 0.02 mSv (2 mrem) in any one hour.

Contamination Surveys

Licensees' contamination surveys should be sufficient to identify areas of contamination that might result in doses to workers or to the public. Combined removable and fixed contamination should be surveyed using appropriate radiation detection equipment. Removable contamination can be detected and measured through a wipe test of the surface, which is counted in an appropriate counting instrument, such as a liquid scintillation counter, a sodium iodide or germanium gamma counter, or a proportional alpha/beta counter.

Contamination surveys should be performed:

- To evaluate radioactive contamination that could be present on surfaces of floors, walls, laboratory furniture, and equipment
- After any spill or contamination event
- When procedures or processes have changed
- To evaluate contamination of users and the immediate work area, at the end of the day, when licensed material is used
- In unrestricted areas at frequencies consistent with the types and quantities of materials in use but not less frequently than quarterly
- In areas adjacent to restricted areas and in all areas through which licensed materials are transferred and temporarily stored before shipment.

Contamination Survey Frequency

Personnel should survey for contamination in locations where individuals are working with an unsealed form of radioactive material in an amount greater than or equal to 10% of the smallest annual limit on intake (ALI) (either the inhalation or ingestion ALI) listed for that radionuclide in **Chapter HFS 157 'Radiation Protection', Appendix E.** These surveys should be done at a frequency appropriate to the types and quantities of radioactive materials in use, but at a minimum quarterly. If amounts are used that are greater than or equal to the smallest ALI listed for that radionuclide in **Chapter HFS 157 'Radiation Protection', Appendix E.** detailed, documented surveys should be performed at least monthly.

Table 9 contains suggested contamination survey frequency from NRC Regulatory Guide 8.23 (See **Tables 10, 11,** and **12** for alternate survey frequencies).

Table 9: Suggested Frequency of Contamination Surveys from NRC Regulatory Guide 8.23

| Areas Where RAM Is Used | | |
|----------------------------------------------------------------|---------|--|
| Areas where > 7.4 MBq (200 μ Ci) is used at any one time | Weekly | |
| Areas where < 7.4 MBq (200 μ Ci) is used at any one time | Monthly | |

Alternate Survey Frequency

Classification of Laboratories

Table 10: Survey Frequency Category

| Group | Low | Medium | High |
|-------|------------------------|-----------------------------------------|---------------------|
| 1 | < 370 kBq (10 μ Ci) | 370 kBq (10 μ Ci) to 37 MBq (1 mCi) | > 37 MBq (1 mCi) |
| 2 | < 37 MBq (1 mCi) | 37 MBq (1 mCi) to 3.7 GBq (100 mCi) | > 3.7 GBq (100 mCi) |
| 3 | < 3.7 GBq (100 mCi) | 3.7 GBq (100 mCi) to 370 GBq (10 Ci) | > 370 GBq (10 Ci) |
| 4 | < 370 GBq (10 Ci) | 370 GBq (10 Ci) to 37 TBq (1000 Ci) | > 37 TBq (1000 Ci) |

Proportional fractions are to be used for more than one isotope.

Table 11: Survey Frequency Category Modifiers

| Modifying Factors | Factors |
|----------------------------------------------------------------------------------------------------|---------|
| Simple storage | x 100 |
| Very simple wet operations (e.g., preparation of aliquots of stock solutions) | x 10 |
| Normal chemical operations (e.g., analysis, simple chemical preparations) | x 1 |
| Complex wet operations (e.g., multiple operations, or operations with complex glass apparatus) | x 0.1 |
| Simple dry operations (e.g., manipulation of powders) and work with volatile radioactive compounds | x 0.1 |
| Exposure of non-occupational persons | x 0.1 |
| Dry and dusty operations (e.g., grinding) | x 0.01 |

The object is to determine how often to survey the laboratory. To do this, multiply the activity range under LOW, MEDIUM, and HIGH survey frequency by the appropriate Modifying Factor to construct a new set of mCi ranges for LOW, MEDIUM, and HIGH survey frequency.

Survey Frequency:

- Low Not less than once a month
- Medium Not less than once per week
- High Not less than once per normal working day.

Table 12: Isotope Groups

| Group 1 | Pb-210, Po-210, Ra-223, Ra-226, Ra-228, Ac-227, Th-227, Th-228, Th-230, Pa-231, U-230, U-232, U-233, U-234, Np-237, Pu-238, Pu-239, Pu-240, Pu-241, Pu-242, Am-241, Am-243, Cm-242, Cm-243, Cm-244, Cm-245, Cm-246, Cf-249, Cf-250, Cf-252 |
|---------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Group 2 | Na-22, Cl-36, Ca-45, Sc-46, Mn-54, Co-56, Co-60, Sr-89, Sr-90, Y-91, Zr-95, Ru-106, Ag-110m, Cd-115m, In-114m, Sb-124, Sb-125, Te-127m, Te-129m, I-124, I-125, I-126, I-131, I-133, Cs-134, Cs-137, Ba-140, Ce-144, Eu-152, Eu-154, Tb-160, Tm-170, Hf-181, Ta-182, Ir-192, Tl-204, Bi-207, Bi-210, At-211, Pb-212, Ra-224, Ac-228, Pa-230, Th-234, U-236, Bk-249 |
| Group 3 | Be-7, C-14, F-18, Na-24, C1-38, Si-31, P-32, P-33, S-35, Ar-41, K-42, K-43, Ca-47, Sc-47, Sc-48, V-48, Cr-51, Mn-52, Mn-56, Fe-52, Fe-55, Fe-59, Co-57, Co-58, Ni-63, Ni-65, Cu-64, Zn-65, Zn-69m, Ga-72, As-73, As-74, As-76, As-77, Se-75, Br-82, Kr-85m, Kr-87, Rb-86, Sr-85, Sr-91, Y-90, Y-92, Y-93, Zr-97, Nb-93m, Nb-95, Mo-99, Tc-96, Tc-97m, Tc-97, Tc-99, Ru-97, Ru-103, Ru-105, Rh-105, Pd-103, Pd-109, Ag-105, Ag-111, Cd-109, Cd-115, In-115m, Sn-113, Sn-125, Sb-122, Te-125m, Te-127, Te-129, Te-131m, Te-132, I-130, I-132, I-134, I-135, Xe-135, Cs-131, Cs-136, Ba-131, La-140, Ce-141, Ce-143, Pr-142, Pr-143, Nd-147, Nd-149, Pm-147, Pm-149, Sm-151, Sm-153, Eu-152, Eu-155, Gd-153, Gd-159, Dy-165, Dy-166, Ho-166, Er-169, Er-171 (9.2 hr), Tm-171, Yb-175, Lu-177, W-181, W-185, W-187, Re-183, Re-186, Re-188, Os-185, Os-191, Os-193, Ir-190, Ir-194, Pt-191, Pt-193, Pt-197, Au-196, Au-198, Au-199, Hg-197, Hg-197m, Hg-203, Tl-200, Tl-201, Tl-202, Pb-203, Bi-206, Bi-212, Rn-220, Rn-222, Th-231, Pa-233, Np-239 |
| Group 4 | H-3, O-15, Ar-37, Co-58m, Ni-59, Zn-69, Ge-71, Kr-85, Sr-85m, Rb-87, Y-9lm, Zr-93, Nb-97, Tc-96m, Tc-99m, Rh-103m, In-113m, I-129, Xe-131m, Xe-133, Cs-134m, Cs-135, Sm-147, Re-187, Os-191m, Pt-193m, Pt-197m, Th-232, Th-Nat, U-235, U-238, U-Nat |

Contamination in Unrestricted Areas

Contamination found in unrestricted areas should be immediately decontaminated to background levels. When it is not possible to get to background levels, the licensee must ensure that the amounts do not exceed the contamination levels listed in **Table 13**.

Table 13 Acceptable Surface Contamination Levels

| Nuclide 1 | Average ^{2,3} | Maximum ^{2, 4} | Removable ^{2,5} |
|---------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------|------------------------------------------------------------------|----------------------------------------------------------------|
| I-125, I-129 | 1.7 Bq/100 cm ² (100 dpm/100 cm ²) | 5.0 Bq/100 cm ² (300dpm/100cm ²) | 0.3 Bq/100 cm ² (20 dpm/100 cm ²) |
| I-126, I-131, I-133, Sr-90 | 16.7 Bq/100 cm ² (1,000 dpm/100 cm ²) | 50.0 Bq/100 cm ² (3,000 dpm/100 cm ²) | 3.3 Bq/100 cm ² (200 dpm/100 cm ²) |
| Beta-gamma emitters (nuclides with decay modes other than alpha emission or spontaneous fission) except Sr-90 and others noted above. | 83.3 Bq/100 cm ² (5,000 dpm/100 cm ²) | 250 Bq/100 cm ² (15,000 dpm /100 cm ²) | 6.7 Bq/100 cm ² (1,000 dpm/100 cm ²) |

¹ Where surface contamination by both alpha- and beta-gamma-emitting nuclides exists, the limits established for alpha- and beta-gamma-emitting nuclides should apply independently.

When equipment or facilities that are potentially contaminated are to be released for unrestricted use, the above table provides the maximum acceptable residual levels. To the extent practicable, it is appropriate to decontaminate to below these levels. Surface contamination surveys should be conducted for both removable and fixed contamination before these facilities or equipment are released from restricted to unrestricted use, to ensure that they meet these limits.

A standardized method for smear testing of a relatively uniform area should be used to aid in comparing contamination at different times and places. A smear taken from an area of about 100 cm² is acceptable to indicate levels of removable contamination.

² As used in this table, dpm (disintegration per minute) means the rate of emission by radioactive material as determined by correcting the counts per minute observed by an appropriate detector for background, efficiency, and geometric factors associated with the instrumentation.

³ Measurements of average contaminant should not be averaged over more than 1 square meter. For objects of less surface area, the average should be derived for each such object.

⁴ The maximum contamination level applies to an area of not more than 100 cm².

⁵ The amount of removable radioactive material per 100 cm² of surface area should be determined by wiping that area with filter or soft absorbent paper, applying moderate pressure, and assessing the amount of radioactive material on the wipe with an appropriate instrument of known efficiency. When removable contamination on objects of less surface area is determined, the pertinent levels should be reduced proportionally and the entire surface should be wiped.

Survey Record Requirements

Each survey record should include the following:

- A diagram of the area surveyed
- A list of items and equipment surveyed
- Specific locations on the survey diagram where wipe test was taken
- Ambient radiation levels with appropriate units
- Contamination levels with appropriate units
- Make and model number of instruments used
- Background levels
- Name of the person making the evaluation and recording the results and date.

Licensees should record contamination levels observed and procedures followed for incidents involving contamination of individuals. The record should include names of individuals involved, description of work activities, calculated dose, probable causes (including root causes), steps taken to reduce future incidents of contamination, times and dates, and the surveyor's signature.

Air Monitoring in the Workplace

Air monitoring can be used to do the following:

- Determine whether the confinement of radioactive materials is effective
- Measure airborne radioactive material concentrations in the workplace
- Estimate worker intakes of radioactive material
- Determine posting requirements
- Determine what protective equipment and measures are appropriate
- Warn of significantly elevated levels of airborne radioactive materials.

If bioassay measurements are used to determine worker doses of record, air sampling may be used to determine time of intake and to determine which workers should have bioassay measurements. The use of engineering controls and a good air sampling program can eliminate the need for bioassays.

Refer to NRC Regulatory Guide 8.25, Revision 1, "Air Sampling in the Workplace," dated June 1992, and NRC NUREG-1400, "Air Sampling in the Workplace," dated September 1993, for further guidance on the air sampling.

Airborne Effluent Release Monitoring

When practicable, airborne radioactive effluents should be released from monitored release points (e.g., monitored stacks, discharges, vents) to provide accurate measurements to estimate public exposure. Licensees should verify the performance of effluent monitoring systems by regular calibration (at least annually) to ensure their reliability.

NRC Regulatory Guide 4.20, "Constraints on Release of Airborne Radioactive Materials to the Environment for Licensees Other Than Power Reactors," dated December 1996, provides guidance on methods acceptable (calculation or COMPLY code) to DHFS for compliance with the constraint on air emissions to the environment.

NRC Regulatory Guide 8.37, "ALARA Levels for Effluents from Materials Facilities," dated July 1993, provides guidance on designing an acceptable program for establishing and maintaining ALARA levels for gaseous and liquid effluents at materials facilities.

For release points for which monitoring is not practicable, the licensee should estimate the magnitude of the unmonitored effluents. These unmonitored releases will occur anytime unsealed material is handled outside a fume hood or other device that will control the releases. The licensee should include these estimates when demonstrating compliance with dose limits and ALARA goals. Unmonitored releases may be estimated based on the quantity of material used in these areas, the number of procedures performed, or other appropriate methods. The unmonitored effluents should not exceed 30% of the total estimated effluent releases or 10% of the permissible air effluent concentrations found in **column 1 of Table 2 in Chapter HFS 157 'Radiation Protection', Appendix E,** whichever is greater.

Effluent monitoring systems should be designed in accordance with ANSI N13.1 (1969), "Document to Sampling Airborne Radioactive Materials in Nuclear Facilities," and ANSI N42.18, "Specification and Performance of On-site Instrumentation for Continuously Monitoring Radioactive Effluents."

Liquid Effluent Release Monitoring

The licensee should evaluate the concentrations of radioactive material in water that is released to the environment and to the sanitary sewer. The licensee must show that these releases meet the limits in *HFS* 157.23(1) and *HFS* 157.30(3), respectively.

The topic of sanitary sewerage releases is more fully discussed in **Appendix V**.

Bioassay Monitoring

Frequency of Required Bioassay Measurements

Determining the appropriate frequency of routine bioassay measurements depends upon the exposure potential and the physical and chemical characteristics of the radioactive material and the route of entry to the body. Consider the following elements:

- Potential exposure of the individual
- Retention and excretion characteristics of the radionuclides
- Sensitivity of the measurement technique
- Acceptable uncertainty in the estimate of intake and committed dose equivalent.

Bioassay measurements used for demonstrating compliance with the occupational dose limits should be conducted often enough to identify and quantify potential exposures and resultant intakes that, during any year, are likely to collectively exceed 0.1 times the ALI. The 10% ALI criterion is consistent with *HFS* 157.25(2), which requires licensees to monitor intakes and assess occupational doses for exposed individuals who are likely to exceed 10% of the applicable limit (i.e., intakes likely to exceed 0.1 ALI for adults).

Separate categories of bioassay measurements, routine measurements and special measurements further determine the frequency and scope of measurements.

Routine Measurements

Routine measurements include baseline measurements, periodic measurements, and termination measurements. These measurements should be conducted to confirm that appropriate controls exist and to

assess dose. The method of bioassay selected (for example, whole body counting, urinalysis, etc.) and the samples collected will vary according to the radionuclides and the compound to which it is attached. Sample collection procedures should be developed to ensure that appropriate types, sizes, and numbers of samples are collected that will provide appropriate physiological information for the dose assessment. An individual's baseline measurement of radioactive material within the body should be conducted before beginning work that involves exposure to radiation or radioactive materials for which monitoring is required.

In addition to the baseline measurements, periodic bioassay measurements should be performed. The frequency of periodic measurements should be based on the likelihood of significant exposure of the individual. In determining the worker's likely exposure, consider such information as the worker's access, work practices, measured levels of airborne radioactive material, and exposure time. Periodic measurements should be made when the cumulative exposure to airborne radioactivity since the most recent bioassay measurement is > 0.02 ALI (40 DAC hours). Noble gases and airborne particulates with a radioactive half-life of less than 2 hours should be excluded from the evaluation, since external exposure generally controls these radionuclides.

At a minimum, periodic measurements should be conducted annually. Periodic measurements provide additional information on any long-term accumulation and retention of radioactive material in the body, especially for exposures to concentrations of airborne radioactive material below monitoring thresholds.

When an individual is no longer subject to the bioassay program because of change in employment status, termination bioassay measurement should be made, when practicable, to ensure that any unknown intakes are quantified.

Special Monitoring

Because of uncertainty in the time of intakes and the absence of other data related to the exposure (e.g., physical and chemical forms, exposure duration), correlating positive results to actual intakes for routine measurements can sometimes be difficult. Abnormal and inadvertent intakes from situations such as a failed respiratory protective device, inadequate engineering controls, inadvertent ingestion, contamination of a wound, or skin absorption, should be evaluated on a case-by-case basis.

When determining whether potential intakes should be evaluated, consider the following circumstances:

- The presence of unusually high levels of facial and/or nasal contamination
- Entry into airborne radioactivity areas without appropriate exposure controls
- Operational events with a reasonable likelihood that a worker was exposed to unknown quantities of airborne radioactive material (e.g., loss of system or container integrity)
- Known or suspected incidents of a worker ingesting radioactive material
- Incidents that result in contamination of wounds or other skin absorption
- Evidence of damage to or failure of a respiratory protective device.

References:

- 1. NRC Regulatory Guide 4.20, "Constraints on Release of Airborne Radioactive Materials to the Environment for Licensees Other Than Power Reactors," dated December 1996.
- 2. NRC Regulatory Guide 8.9, Revision 1, "Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program," dated July 1993.
- 3. NRC Regulatory Guide 8.23, Revision 1, "Radiation Safety Surveys at Medical Institutions," dated January 1981.
- 4. NRC Regulatory Guide 8.25, Revision 1, "Air Sampling in the Workplace," dated June 1992.
- 5. NRC Regulatory Guide 8.32, "Criteria for Establishing a Tritium Bioassay Program," dated July 1988.
- 6. NRC Regulatory Guide 8.37, "ALARA Levels for Effluents from Materials Facilities," dated July 1993.
- 7. NRC NUREG-1400, "Air Sampling in the Workplace," dated September 1993.
- 8. NRC NUREG/CR- 4884, "Interpretation of Bioassay Measurements," dated July 1987.
- 9. ANSI N13.1 (1969), "Document to Sampling Airborne Radioactive Materials in Nuclear Facilities," dated 1991.
- 10. ANSI N13.30-1996, "Performance Criteria for Radiobioassay," dated 1996.
- 11. ANSI N42.18, "Specification and Performance of On-site Instrumentation for Continuously Monitoring Radioactive Effluents," 1991.
- 12. NCRP Commentary No. 3, "Screening Techniques for Determining Compliance with Environmental Standards," published in January, 1989, and the addendum published in October, 1989.
- 13. U.S. Department of Energy, DOE G 441.1-8, "Air Monitoring Guide," March 17, 1999.
- 14. U.S. Department of Energy, DOE G 441.1-3, "Internal Dosimetry Program Guide," March 17, 1999.
- 15. U.S. Department of Energy, DOE G 441.1-4, "External Dosimetry Program Guide," March 17, 1999.
- 16. U.S. Department of Energy, DOE G 441.1-2, "Occupational ALARA Program Guide," March 17, 1999.

Appendix T:

Leak Test Procedures

This appendix provides applicants and licensees with leak test procedures and sample calculations for determining activity on a wipe test sample.

Frequency for Conducting Leak Tests of Sealed Sources

Leak tests will be conducted at the frequency specified in the respective SSD Registration Certificate.

Procedure for Performing Leak Testing and Analysis

For each source to be tested, list identifying information such as manufacturer, model number, serial number, radionuclide, and activity.

• Use a survey meter to monitor exposure, if appropriate.

• Prepare a separate wipe sample (e.g., cotton swab or filter paper) for each source.

• Number each wipe to correlate with identifying information for each source.

• Wipe the most accessible area (but not directly from the surface of a source) where contamination would accumulate if the sealed source were leaking.

• Select an instrument that is sensitive enough to detect 185 becquerels (0.005 microcurie) of the radionuclide and ensure that its calibration is current.

• Using the selected instrument, count and record background count rate.

• Calculate efficiency of the detector. A sample calculation is shown below.

• Count the sample.

For example: [(cpm from std) - (cpm from bkg)] = efficiency in cpm/Bq

Activity of std in Bq

where:

cpm = counts per minute

std = standard

bkg = background

Bq = becquerels

• Count each wipe sample; determine net count rate.

• For each sample, calculate and record estimated activity in becquerels (or microcuries).

For example: [(cpm from wipe sample) - (cpm from bkg)] = Bq on wipe sample

efficiency in cpm/Bq

- Sign and date the list of sources, data and calculations. Retain records for 3 years (**HFS 157.31(3)).**
- If the wipe test activity is 185 Bq (0.005 mCi) or greater, notify the RSO, so that the source can be withdrawn from use and disposed of properly.
- Notify DHFS.

Appendix U:

Transportation Requirements

The major areas in the DOT regulations that are most relevant for transportation of licensed material shipped as Type A quantities are as follows:

- Hazardous Materials Table, **49 CFR 172.101, App. A**, *List of Hazardous Substances and Reportable Quantities (RQ), Table 2: Radionuclides*
- Shipping Papers **49 CFR 172.200-204**: General entries, description, additional description requirements, shipper's certification
- Package Markings 49 CFR 172.300, 49 CFR 172.301, 49 CFR 172.303, 49 CFR 172.304, 49
 CFR 172.310, 49 CFR 172.324: General marking requirements for non-bulk packaging,
 prohibited marking, marking requirements, radioactive material, hazardous substances in non-bulk packaging
- Package Labeling 49 CFR 172.400, 49 CFR 172.401, 49 CFR 172.403, 49 CFR 172.406, 49 CFR 172.407, 49 CFR 172.436, 49 CFR 172.438, 49 CFR 172.440: General labeling requirements, prohibited labeling, radioactive materials, placement of labels, specifications for radioactive labels
- Placarding of Vehicles 49 CFR 172.500, 49 CFR 172.502, 49 CFR 172.504, 49 CFR 172.506, 49
 CFR 172.516, 49 CFR 172.519, 49 CFR 172.556: Applicability, prohibited and permissive placarding, general placarding requirements, providing and affixing placards: highway, visibility and display of placards, specifications for RADIOACTIVE placards
- Emergency Response Information, Subpart G, 49 CFR 172.600, 49 CFR 172.602, 49 CFR
 172.604: Applicability and general requirements, emergency response information, emergency response telephone number
- Training, **Subpart H, 49 CFR 172.702, 49 CFR 172.704:** Applicability and responsibility for training and testing, training requirements
- Shippers General Requirements for Shipments and Packaging, **Subpart I, 49 CFR 173.403, 49 CFR 173.410, 49 CFR 173.412, 49 CFR 173.415, 49 CFR 173.431, 49 CFR 173.433, 49 CFR 173.435, 49 CFR 173.441, 49 CFR 173.443, 49 CFR 173.448, 49 CFR 173.475, 49 CFR 173.476:** Definitions, general design requirements, additional design requirements for Type A packages, authorized Type A packages, activity limits for Type A packages, requirements for determining A₁ and A₂, table of A₁ and A₂ values for radionuclides, radiation level limitations,

contamination control, general transportation requirements, quality control requirements prior to each shipment, approval of special form radioactive materials.

Carriage by Public Highway - General Information and Regulations, Subpart A, 49 CFR
 177.816, 49 CFR 177.817, 49 CFR 177.834(a), 49 CFR 177.842: Driver training, shipping paper, general requirements (secured against movement), Class 7 (radioactive) material.

Hazard Communications for Class 7 (Radioactive) Materials DOT Shipping Papers (49 CFR 172.200-205)

NOTE: IAEA, ICAO, and IMO may require additional hazard communication information for international shipments. This table must not be used as a substitute for the DOT and NRC regulations on the transportation of radioactive materials.

| Entries Always Required Unless Excepted | Additional Entries Sometimes Required | Optional Entries | |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|
| The basic description, In sequence: Proper Shipping Name, Hazard Class (7), U.N. Identification Number 24 hour emergency response telephone number Name of shipper Proper page numbering (Page 1 of 4) Except for empty and bulk packages, the total quantity (mass, or volume for liquid), in appropriate units (lbs, mt) If not special form, chemical and physical form The name of each Radionuclides (95% rule) and total package activity. The activity must be in SI units (e.g., Bq, TBq), or both SI units and customary units (e.g., Ci, mCi). However, for domestic shipments, the activity may be expressed in terms of customary units only, until 4/1/97. For each labeled package: The category of label used; The transport index of each package with a Yellow-II or Yellow-III label Shipper's certification (not required of private carriers) | Materials-Based Requirements: If hazardous substance, "RQ" as part of the basic description The LSA or SCO group (e.g., LSA-II) "Highway Route Controlled Quantity" as part of the basic description, if HRCQ Fissile material information (e.g., "Fissile Exempt," controlled shipment statement [see §172.203(d)(7)]) If the material is considered hazardous waste and the word waste does not appear in the shipping name, then "waste" must precede the shipping name (e.g., Waste Radioactive Material, nos, UN2982) "Radioactive Material" if not in proper shipping name Package-Based Requirements: Package identification for DOT Type B or NRC certified packages IAEA CoC ID number for export shipments or shipments using foreign-made packaging (see §173.473) Administrative-Based Requirements: "Exclusive Use-Shipment" Instructions for maintenance of exclusive use-shipment controls for LSA/SCO strong-tight or NRC certified LSA (§ 173.427) If a DOT exemption is being used, "DOT-E" followed by the exemption number | The type of packaging (e.g., Type A, Type B, IP-1,) The Technical/chemical name may be in included (if listed in §172.203(k), in parentheses between the proper shipping name and hazard class; otherwise inserted in parenthesis after the basic description) Other information is permitted (e.g., functional description of the product), provided it does not confuse or detract from the proper shipping name or other required information For fissile radionuclides, except Pu-238, Pu-239, and Pu-241, the weight in grams or kilograms may be used in place of activity units. For Pu-238, Pu-239, and Pu-241, the weight in grams or kilograms may optionally be entered in addition to activity units [see § 172.203(d)(4)] Emergency response hazards and guidance information (§§ 172.600-604) may be entered on the shipping papers, or may be carried with the shipping papers [§ 172.602(b)] | |

Some Special Considerations/Exceptions for Shipping Paper Requirements

- Shipments of Radioactive Material, excepted packages, under UN2910 (e.g., Limited Quantity, Empty packages, and Radioactive Instrument and Article), are excepted from shipping papers. For limited quantities (§173.421), this is only true if the limited quantify is not a hazardous substance (RQ) or hazardous waste (40 CFR 262)
- Shipping papers must be in the pocket on the left door, or readily visible to person entering driver's compartment and within arm's reach of the driver
- For shipments of multiple cargo types, any HAZMAT entries must appear as the first entries on the shipping papers, be
 designated by an "X" (or "RQ") in the hazardous material column, or be highlighted in a contrasting color

Hazard Communications for Class 7 (Radioactive) Materials

Marking Packages (49 CFR 172.300-338)

NOTE: IAEA, ICAO, and IMO may require additional hazard communication information for international shipments.

This table must not be used as a substitute for the DOT and NRC regulations on the transportation of radioactive materials.

Markings Always Required Additional Markings Sometimes Required Optional Markings Unless Excepted "IP-1." "IP-2." or "IP-Non-Bulk Packages Materials-Based Requirements 3" on industrial Proper shipping name If in excess of 110 lbs (50 kg), Gross Weight packaging is recommended U.N. identification number If non-bulk liquid package, underlined double arrows indicating upright orientation (two opposite sides) [ISO Std 780-1985 marking] Both the name and Name and address of consignor or address of consignor and consignee are consignee, unless: 1. highway only and no motor If a Hazardous substance in non-bulk package, the recommended letters "RQ" in association with the proper shipping name carrier transfers; or part of carload or truckload lot or Other markings (e.g., advertising) freight container load, and entire Package-Based Requirements contents of railcar, truck, or freight are permitted, but must be sufficiently container are shipped from one The package type if Type A or Type B (1/2" or greater letters) consignor to one consignee [see away from required The specification-required markings [e.g., for Spec. 7A packages: "DOT 7A Type A" and "Radioactive Material" (see §178.350.353)] §172.301(d)] markings and labeling Bulk Packages (i.e., net capacity For approved packages, the certificate ID number greater than 119 gallons as a (e.g., USA/9166/B(U), USA/9150/B(U)-85, ...) receptade for liquid, or 119 gallons and 882 pounds as a receptacle for If Type B, the trefoil (radiation) symbol per Part 172 App. B [size: solid, or water capacity greater than outer radius > 20 mm (0.8 in)] 1000 lbs, with no consideration of intermediate forms of containment) For NRC certified packages, the model number, gross weight, and package ID number (10 CFR 71.85) U.N. identification number, on orange, rectangular panel (see Administrative-Based Requirements §172.332) - some exceptions exist If a DOT exemption is being used, "DOT-E" followed by the exemption number If an export shipment, "USA" in conjunction with the specification markings or certificate markings

Some Special Considerations/Exceptions for Marking Requirements

- Marking is required to be: (1) durable, (2) printed on a package, label, tag, or sign, (3) unobscured by labels or attachments, (4) isolated from other marks, and (5) be representative of the hazmat contents of the package.
- Limited Quantity (§173.421) packages and Articles Containing Natural Uranium and Thorium (§173.426) must bear the marking
 "radicactive" on the outside of the inner package or the outer package itself, and are excepted from other marking. The excepted
 packages shipped under UN 2910 must also have the accompanying statement that is required by §173.422.
- Empty (§173.428) and Radioactive Instrument and Article (§173.424) packages are excepted from marking.
- Shipment of LSA or SCO required by §173.427 to be consigned as exclusive use are excepted from marking except that the exterior of
 each nonbulk package must be marked "Radioactive-LSA" or "Radioactive-SCO," as appropriate. Examples of this category are
 domestic, strong-tight containers with less than an A₂ quantity, and domestic NRC certified LSA/SCO packages using 10 CFR 71.52.
- For bulk packages, marking may be required on more than one side of the package (see 49 CFR 172.302(a)).

Hazard Communications for Class 7 (Radioactive) Materials

Labeling Packages (49 CFR 172.400-450)

NOTE: IAEA, ICAO, and IMO may require additional hazard communication information for international shipments This table must not be used as a substitute for the DOT and NRC regulations on the transportation of radioactive materials

Placement of Radioactive Labels

- Labeling is required to be: (1) placed near the required marking of the proper shipping name, (2) printed or affixed to the package surface (not the bottom), (3) in contrast with its background, (4) unobscured by markings or attachments, (5) within color, design, and size tolerance, and (6) representative of the HAZMAT contents of the
- For labeling of radioactive materials packages, two labels are required on opposite sides excluding the bottom

| | | Determination of Requ | ired Label | |
|--------------------------------------------------------------------|-----------------------------------------------------------------|-----------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|
| Size: Sides: ≥ 100 mm (3.9 in.) Border: 5-6.3 mm (0.2- 0.25 in.) | RADIOACTIVE I | RADIOACTIVE 11 | RADIOACTIVE BBI | EMPTY 5 in. |
| L | 49 CFR 172.436 | 49 CFR 172.438 | 49 CFR 172.440 | 49 CFR 172.450 |
| Label | WHITE-I | YELLOW-II | YELLOW-III | EMPTY LABEL |
| Required when: | Surface radiation level < 0.005 mSv/hr (0.5 mrem/hr) | 0.005 mSv/hr (0.5 mrem/hr) < surface radiation level ≤ 0.5 mSv/hr (50 mrem/hr) | 0.5 mSv/hr (50 mrem/hr) < surface radiation level < 2 mSv/hr (200 mrem/h) [Note: 10 mSv/hr (1000 mrem/hr) for exclusive-use closed vehicle (§173.441(b)] | The EMPTY label is required for shipments of empty Class 7 (radioactive) packages made pursuant to |
| <u>Or:</u> | TI = 0 [1 meter dose rate < 0.0005 mSv/hr (0.05 mrem/hr)] | TI < 1 [1 meter dose rate < 0.01 mSv/hr (1 mrem/hr)] | TI < 10 [1 meter dose rate < 0.1 mSv/hr (10 mrem/hr)] [Note: There is no package TI limit for exclusive-use] | §173.428. It must cover any previous labels, or they must be removed or obliterated. |
| Notes: | Although radiation le | 0 0 1 | olled Quantity (HRCQ) must be re shown above, for fissile ma introl | |

Content on Radioactive Labels

- RADIOACTIVE Label must contain (entered using a durable, weather-resistant means):

 - The radionuclides in the package (with consideration of available space). Symbols (e.g., Co-60) are acceptable
 The activity in SI units (e.g., Bq, TBq), or both SI units with customary units (e.g., Ci, mCi) in parenthesis.
 However, for domestic shipments, the activity may be expressed in terms of customary units only, until 4/1/97.
 The Transport Index (TI) in the supplied box. The TI is entered only on YELLOW-II and YELLOW-III labels

Some Special Considerations/Exceptions for Labeling Requirements

- For materials meeting the definition of another hazard class, labels for each secondary hazard class need to be affixed to the package. The subsidiary label may not be required on opposite sides, and must not display the hazard class
- to the package. The Substituty Russiansy Russi

Hazard Communications for Class 7 (Radioactive) Materials

Placarding Vehicles (49 CFR 172.500-560)

NOTE: IAEA, ICAO, and IMO may require additional hazard communication information for international shipments.

This table must not be used as a substitute for the DOT and NRC regulations on the transportation of radioactive materials.

Visibility and Display of Radioactive Placard

- Placards are required to be displayed:
 - On four sides of the vehicle;
 - Visible from the direction they face, (for the front side of trucks, tractor-front, trailer, or both are authorized);
 - Clear of appurtenances and devices (e.g., ladders, pipes, tarpaulins);
 - At least 3 inches from any markings (such as advertisements) which may reduce placard's effectiveness;
 - Upright and on-point such that the words read horizontally;
 - In contrast with the background, or have a lined-border which contrasts with the background;
 - Such that dirt or water from the transport vehicle's wheels will not strike them;
 - Securely attached or affixed to the vehicle, or in a holder.
- Placard must be maintained by carrier to keep color, legibility, and visibility.

Conditions Requiring Placarding

- Placards are required for any vehicle containing a package with a RADIOACTIVE Yellow-III label.
- Placards are required for shipment of LSA or SCO required by §173.427 to be consigned as exclusive use. Examples of this
 category are domestic, strong-tight containers with less than an A₂ quantity, and domestic NRC certified LSA/SCO packages
 using 10 CFR 71.52. Also, for bulk packages of these materials, the orange panel marking with the UN Identification number is
 not required.
- Placards are required for any vehicle containing a package with a Highway Route Controlled Quantity (HRCQ). In this case, the
 placard must be placed in a square background as shown below (see §173.507(a)).

Radioactive Placard Size Specs: Sides: > 273 mm (10.8 in.) Solid line Inner RADIOACTIVE border: About 12.7 mm (0.5 in.) from edges Lettering: > 41 mm (1.6 in.) 49 CFR 172.556 IAEA SS 6 (1985) paras. 443-444 See 49 CFR 172.527 AND 556 Square for RADIOACTIVE PLACARD RADIOACTIVE PLACARD RADIOACTIVE PLACARD FOR HRCQ: 387mm (International) HIGHWAY ROUTE CONTROLLED (Domestic) (15.25 in.) QUANTITY outside length by Base of yellow solid area: (either domestic or international 25.4 mm (1 in.) 29 + 5 mm (1.1 + 0.2 in.) above placard could be in middle) thick horizontal centerline

| Quantity: | < 70 Bq/g (< 0.002 μCi/g) (| Limited Quantity §173.421) (§ | A ₁ /A ₂ value 173.435) | 1 rem/hr at 3 m un-shielded (§173.427) |
|---------------------------------------------------------------------------------------|--------------------------------|----------------------------------|--------------------------------------------------|----------------------------------------------|
| Non-LSA/SCO: | Excepted | Type A | Тур | oe B ³ |
| Domestic or International LSA/SCO: LSA-I solid, (liquid) ¹ SCO-I | | IP-I | | Type B ³ |
| LSA-I Liquid LSA-II Solid, (liquid or gas) ¹ (LSA-III) ¹ SCO-II | Excepted | IP-II | Ì | Type B ³ |
| LSA-II Liquid or Gas LSA-III | 10 3 (4 | IP-III | į. | Type B ³ |
| Domestic (only) LSA/SCO: | 20 00 | 77 | 207.0 | Type B ³ |
| LSA-I, II, III; SCO-I, II | Excepted | Strong-tight ² | DOT Spec. | NRC Type A LSA 3,4 |

- For entries in parentheses, exclusive use is required for shipment in an IP (e.g., shipment of LSA-I liquid in an IP-I packaging would require exclusive-use consignment)
 Exclusive use required for strong-tight container shipments made pursuant to §173.427(b)(2)
 Subject to conditions in Certificate, if NRC package
 Exclusive use required, see §173.427(b)(4). Use of these packages expires on 4/1/99 (10 CFR 71.52)

| | | | nits (49 CFR 173.441) ^A ons on the transportation of ra | dioactive materials |
|-----------------------------------------------|---------------------------|------------------------------------------------|-----------------------------------------------------------------------|-------------------------------------------------------|
| Transport Vehicle Use: | Non-Exclusive | | Exclusive | |
| Transport Vehicle Type: | Open or Closed | Open (flat-bed) | Open w/Enclosure ^B | Closed |
| Package (or freight container) Limi | ts: | | ** | |
| External Surface | 2 mSv/hr (200 mrem/hr) | 2 mSv/hr (200 mrem/hr) | 10 mSv/hr (1000 mrem/hr) | 10 mSv/hr (1000 mrem/hr) |
| Transport Index (TI) ^c | 10 | | no limit | |
| Roadway or Railway Vehicle (or fr | eight container) Limit | s: | | |
| Any point on the outer surface | | N/A | N/A | 2 mSv/hr (200 mrem/hr) |
| Vertical planes projected from outer edges | N/A | 2 mSv/hr (200 mrem/hr) | 2 mSv/hr (200 mrem/hr) | N/A |
| Top of | | load: (200 mrem/hr) | enclosure: 2 mSv/hr (200 mrem/hr) | vehicle: 2 mSv/hr (200 mrem/hr) |
| 2 meters from | | vertical planes: 0.1 mSv/hr (10 mrem/hr) | vertical planes: 0.1 mSv/hr (10 mrem/hr) | outer lateral surfaces: 0.1 mSv/hr (10 mrem/hr) |
| Underside | | | 2 mSv/hr (200 mrem/hr) | |
| Occupied position | N/A ^D | 0.02 mSv/hr (2 mrem/hr) ^E | | |
| Sum of package Ti's | 50 | no limit ^F | | |

- A. The limits in this table do not apply to excepted packages see 49 CFR 173.421-426.
- Securely attached (to vehicle), access-limiting enclosure; package personnel barriers are considered as enclosures.
 For nonfissile radioactive materials packages, the dimensionless number equivalent to maximum radiation level at 1 m (3.3 feet) from the exterior package surface, in millirem/hour.
- D. No dose limit is specified, but separation distances apply to Radioactive Yellow-II or Radioactive Yellow-III labeled packages.
- E. This does not apply to private carrier wearing dosimetry if under radiation protection program satisfying 10 CFR 20 or 49 CFR 172 Subpart I.

 F. Some fissile shipments may have combined conveyance TI limit of 100 see 10 CFR 71.59 and 49 CFR 173.457.

Package and Vehicle Contamination Limits (49 CFR 173.443)

This table must not be used as a substitute for the DOT and NRC regulations on the transportation of radioactive materials

NOTE: All values for contamination in DOT rules are to be averaged over each 300 cm²
Sufficient measurements must be taken in the appropriate locations to yield representative assessments

6γ means the sum of beta emitters, gamma emitters, and low-toxicity alpha emitters

" means the sum of all other alpha emitters (i.e., other than low-toxicity alpha emitters)

The Basic Contamination Limits for All Packages: 49 CFR 173.443(a), Table 11 General Requirement: Non-fixed (removable) contamination must be kept as low as reasonably achievable (ALARA)

 6γ : 0.4 Bq/cm² = 40 Bq/100 cm² = 1x10⁻⁵ μCi/cm² = 2200 dpm/100 cm²

 α : 0.04 Bq/cm² = 4 Bq/100 cm² = 1x10⁶ μ Ci/cm² = 220 dpm/100 cm²

| ў 4 | The followin | g exceptions and deviations from the above basic limits exist: |
|-----------------------------------------------------------------|----------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Deviation from Basic Limits | Regulation 49 CFR §§ | Applicable Location and Conditions Which must Be Met: |
| 10 times the basic limits | 173.443(b) and 173.443(c) | On any external surface of a package in an exclusive use shipment, during transport including end of transport. Conditions include: Contamination levels at beginning of transport must be below the basic limits. |
| | Also see 177.843 (highway) | Vehicle must not be returned to service until radiation level is shown to be ≤ 0.005 mSv/hr (0.5 mrem/hr) at any accessible surface, and there is no significant removable (non-fixed) contamination. |
| 10 times the basic limits 173.443(d) Also see 177.843 (highway) | | On any external surface of a package, at the beginning or end of transport, if a closed transport vehicle is used, solely for transporting radioactive materials packages. Conditions include: A survey of the interior surfaces of the empty vehicle must show that the radiation level at any point does not exceed 0.1 mSv/hr (10 mrem/hr) at the surface, or 0.02 mSv/hr (2 mrem/hr) at 1 meter (3.3 ft). |
| | | Exterior of vehicle must be conspicuously stenciled, "For Radioactive Materials Use Only" in letters at least 76 mm (3 inches) high, on both sides. |
| | | Vehicle must be kept closed except when loading and unloading. |
| 100 times the basic limits | 173.428 | Internal contamination limit for excepted package-empty packaging, Class 7 (Radioactive) Material, shipped in accordance with 49 CFR 173.428. Conditions include: (1) The basic contamination limits (above) apply to external surfaces of package. (2) Radiation level must be ≤ 0.005 mSv/hr (0.5 mrem/hr) at any external surface. (3) Notice in §173.422(a)(4) must accompany shipment. (4) Package is in unimpaired condition & securely closed to prevent leakage. (5)Labels are removed, obliterated, or covered, and the "empty" label (§172.450) is affixed to the package. |

In addition, after any incident involving spillage, breakage, or suspected contamination, the modal-specific DOT regulations (§177.861(a), highway; §174.750(a), railway; and §175.700(b), air) specify that vehicles, buildings, areas, or equipment have "no significant removable surface contamination" before being returned to service or routinely occupied. The carrier must also notify offeror at the earliest practicable moment after incident.

Example Certificate Enclosed In/or on Package, Included with the Packing List or Otherwise Forwarded with the Package

| This package conforms to the conditions, and limitations specified in 49 CFR 173.424 for |
|------------------------------------------------------------------------------------------|
| radioactive material, excepted package-instruments or articles, UN2910. |
| |
| |
| (Signed) Radiation Safety Officer |

Appendix V:

Sample Waste Management Procedures

General Guidelines

- All radioactivity labels must be defaced or removed from containers and packages prior to disposal into ordinary "non-radioactive" waste streams. If waste is compacted, all labels that are visible in the compacted mass must be defaced or removed.
- 2. Remind workers that nonradioactive waste such as leftover reagents, boxes, and packaging material should not be mixed with radioactive waste.
- Occasionally monitor all procedures to ensure that radioactive waste is not created unnecessarily.
 Review all new procedures to ensure that waste is handled in a manner consistent with established procedures.
- 4. In all cases, consider the entire impact of various available disposal routes. Consider occupational and public exposure to radiation, other hazards associated with the material and routes of disposal (e.g., toxicity, carcinogenicity, pathogenicity, flammability), and costs.
- 5. Waste management program should include waste handling procedures for the users within their laboratories or assigned areas, and for waste handlers who may collect waste from areas of use to bring to the storage area for eventual disposal.
- 6. Housekeeping staff should be provided adequate training to avoid the possibility of unauthorized disposal or exposure of these individuals to radioactive materials or to radiation.

Sample Procedure for Disposal by Decay-in-Storage (DIS)

Applicants should assure that adequate space and facilities are available for the storage of waste for DIS. Licensees can minimize the need for storage space if the waste is segregated according to physical half-life.

- 1) Only short-lived waste (physical half-life of less than or equal to 120 days) may be disposed of by DIS.
- 2) Short-lived waste should be segregated from long-lived waste.
- 3) Waste should be stored in suitable well-marked containers, and the containers should provide adequate shielding.

- 4) Liquid and solid wastes must be stored separately.
- 5) When the container is full, it should be sealed. The sealed container should be identified with a label affixed or attached to it.
- 6) The identification label should include the date when the container was sealed, the longest-lived radioisotope in the container, total activity, date when ten half-lives of the longest-lived radioisotope will have transpired, and the initials of the individual who sealed the container. The container may be transferred to the DIS area. When large quantities are held for DIS, sufficient quantities may be present even after 10 half-lives that persons performing surveys should be aware of the potential for measurable radiation.
- 7) The contents of the container should be allowed to decay for at least ten half-lives of the longest-lived radioisotope in the container.
- 8) Prior to disposal as ordinary trash, each container should be monitored as follows:
 - a) Check the radiation detection survey meter for proper operation.
 - b) Survey the contents of each container in a low background area.
 - c) Remove any shielding from around the container.
 - d) Monitor all surfaces of the container.
 - e) Discard the contents as ordinary trash only if the surveys of the contents indicate no residual radioactivity, i.e. surface readings are indistinguishable from background.
 - f) If the surveys indicate residual radioactivity, return the container to DIS area and contact the RSO for further instructions.
- 9) If the surveys indicate no residual radioactivity, record the date when the container was sealed, the disposal date, type of waste (used or unused material, gloves, etc.), survey instrument used, and the initials of the individual performing surveys and disposing of the waste.

All radiation labels must be defaced or removed from containers and packages prior to disposal as ordinary trash. Syringes/needles placed into sealed waste containers for decay do not need the labels removed, provided that the following is done: waste barrels are sealed prior to delivery to the waste disposal firm and delivered directly from the licensee's facility; labels are removed from the waste barrels/containers; and that the waste is incinerated, not placed in a landfill; and the waste disposal firm is cautioned not to open the container prior to incineration.

Sample Procedure for Disposal of Liquids into Sanitary Sewerage

- 1) Confirm that the sewer system is a public system, not a private sanitary sewer, septic system or leach field.
- 2) Confirm that the liquid waste being discharged is soluble (or is biological material that is readily dispersible) in water.
- 3) Calculate the amount of each radioisotope that can be discharged by using the information from prior, similar discharges and the information in **Chapter HFS 157 'Radiation Protection', Appendix E**
- 4) Make sure that the amount of each radioisotope does not exceed the monthly and annual discharge limits specified in *HFS 157.30(3)* and **HFS 157 'Radiation Protection', Appendix E, Table 3** (records for individual users/laboratories).
- 5) If more than one radioisotope is released, the sum of the ratios of the average monthly discharge of a radioisotope to the corresponding limit in HFS 157 'Radiation Protection', Appendix E, Table 3 must not exceed unity.
- 6) Total quantity of licensed material released into the sanitary sewerage system in a year does not exceed 185 GBq (5 Ci) of H-3 (tritium), 37 GBq (1 Ci) of C-14, and 37 GBq (1 Ci) of all other radioisotopes combined.
- 7) Record the date, radioisotope(s), estimated activity of each radioisotope, location where the material is discharged, and the initials of the individual discharging the waste.
- 8) Liquid waste should be discharged only via designated sinks or toilets.
- 9) Discharge liquid waste slowly to minimize splashing with water running, to be sure that the material moves out of the sink and into the sewer system.

- 10) Survey the sink and surrounding work surfaces to confirm that no residual material or contamination remained in the sink or on work surfaces. Decontaminate as appropriate.
- 11) Decontaminate all areas or surfaces if found to be contaminated.
- 12) For all releases to the sanitary sewer from the licensed facility, maintain records of each radioisotope and its quantity and concentration that is released into the sewer system that demonstrate compliance with the regulatory limits for total quantity released and concentrations released by the licensed facility.

Sample Procedure for Incineration

These guidelines apply to noncommercial waste disposal, i.e., incineration of a licensee's own waste. You do not need specific DHFS approval in order to incinerate certain categories of radioactive waste. For example, *HFS 157.30(5)* provides that tritium and carbon-14 in low level concentrations in liquid scintillation media and animal tissue may be disposed of without regard to radioactivity. After you review your program and confirm that you have waste that requires specific DHFS approval for incineration, please provide the following information.

- 1. Describe the training and experience of the person who will be responsible for the on-site and day-to-day supervision of incinerator operations.
- 2. Describe the waste that is proposed to be incinerated, to include: the chemical and/or physical form of the waste containing licensed material and a description of how the waste is segregated, packaged and labeled for transfer from the generation site to the incinerator; the name of the radioisotope; concentration of radioactivity averaged over the weight of the material to be incinerated (microcuries per gram of waste medium) for each isotope to be incinerated; and the total radioactivity of each isotope per burn and the total number of burns per year. Describe procedures for ensuring that these frequencies and activities will not be exceeded.
- 3. Describe the procedures for packaging, handling, securing and monitoring of waste to prevent contamination and/or unnecessary exposure to personnel or property during the waste life cycle.
- 4. Describe your method for measuring or estimating the concentration of radioactive material remaining in the ash residue. Describe your procedures for collection, handling and disposal of the ash residue.

- 5. Describe the recordkeeping procedures for the waste incineration program. Records must be adequate to document all receipts, incinerations, environmental releases of effluents, and any disposals of ash generated in the incineration process. These records must be maintained in the same units as applicable rules.
- 6. Describe the characteristics of the incinerator and site location, including: height of the stack, rated air flow (cubic feet per hour or similar units), proximity of the stack or other discharge to occupied areas (e.g., residences, school, hospital), and distance to the nearest air intake ducts of adjacent buildings. Describe any scrubbers, filters, or air cleaning equipment that is present.
- 7. State how the concentration of radionuclides released, both as airborne effluent and as any liquid effluent from scrubbers, condensers, or associated systems, will be measured or otherwise determined. Describe any stack monitoring that is planned.
- 8. Provide a copy of the written safety analysis that demonstrates the applicant will be able to incinerate the types and quantities of radioactivity specified in the application without exceeding the environmental release limits specified in **Chapter HFS 157 'Radiation Protection'**.
- 9. Provide a written commitment that the applicant has coordinated with appropriate State and local authorities and that such permits and other authorizations as may be necessary have been obtained.
- 10. Provide a copy of the radiation safety procedures for monitoring personnel involved in incineration operations and for monitoring all effluent generated by the incineration process. The procedures must ensure that regulatory limits for environmental releases of radioactivity will not be exceeded. The applicant must describe how any ash generated exceeding regulatory limits will be disposed of.

Compaction of Waste

The following information should be provided from licensees who propose to compact waste.

- 1. Describe the compactor to demonstrate that it is adequately designed and manufactured to safely compact the type and quantity of waste generated during licensed operations (e.g., manufacturer's specifications, annotated sketches, photographs, etc.).
- 2. Describe the type, quantities, and concentrations of waste to be compacted.
- 3. Provide an analysis of the potential for airborne release of radioactive material during compaction activities.

- 4. State the location of the compactor(s) within the waste processing area(s), as well as a description of the ventilation and filtering systems used in conjunction with the compactors. Include a description of the procedures for monitoring filter blockage and exchange.
- 5. Discuss the methods used to monitor worker breathing zones and/or exhaust systems.
- 6. Discuss the types and frequencies of surveys that will be performed for contamination control in the compactor area.
- 7. Discuss the instruction provided to compactor operators, including instructions for protective clothing; checks for proper functioning of equipment; method of handling uncompacted waste; and examining containers for defects.